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COMBINED TRANSMITTAL OF APPEAL BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES & PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. 1.136(a) (Large Entity)	Docket No. 98.21US

In Re Application Of: **Shah et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/324,182	**June 2, 1999**	**Pulliam, Amy**	**1615**

Invention: **Non-Tacky Mascara Composition**

TO THE COMMISSIONER FOR PATENTS:

This combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition for extension of time under 37 CFR 1.136(a) is respectfully submitted by the undersigned:

Signature

Dated: **January 28, 2004**

Dorene M. Price (Reg. No. 43,018)
Estee Lauder Companies
125 Pinelawn Road
Melville, NY 11747
(631) 531-1194

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COMBINED TRANSMITTAL OF APPEAL BRIEF TO THE BOARD OF PATENT APPEALS AND INTERFERENCES & PETITION FOR EXTENSION OF TIME UNDER 37 C.F.R. 1.136(a) (Large Entity)	Docket No. 98.21US

In Re Application Of: **Shah et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/324,182	June 2, 1999	Pulliam, Amy	1615

Invention: **Non-Tacky Mascara Composition**

TO THE COMMISSIONER FOR PATENTS:

This is a combined Transmittal of Appeal Brief to the Board of Patent Appeals and Interferences and petition under the provisions of 37 CFR 1.136(a) to extend the period for filing an Appeal Brief. The Appeal Brief is transmitted in triplicate with respect to the Notice of Appeal filed on October 28, 2003.

Applicant(s) hereby request(s) an extension of time of (check desired time period):

☒ One month ☐ Two months ☐ Three months ☐ Four months ☐ Five months

from: **December 28, 2003** (*Date*) until: **January 28, 2004** (*Date*)

The fee for the Appeal Brief and Extension of Time has been calculated as shown below:

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Serial No. 09/324,182	Filing Date June 2, 1999	Examiner Pulliam, Amy	Group Art Unit 1615

Invention: Non-Tacky Mascara Composition

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Attorney Docket No.: 98.21US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

APPELLANT'S BRIEF PURSUANT TO 37 CFR 1.191 AND 1.192

Assistant Commissioner of Patents and Trademarks

Attention: Board of Patent Appeals and Interferences

Washington, D.C. 20231

Dear Sir:

Applicants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1 to 8, and 10 to 30 in the present application in the decision of May 28, 2003.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Color Access, Inc., the assignee of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences relating to the instant application that would directly affect, be directly affected by, or have a bearing of any kind on the Board's decision in this appeal that are known to Appellants.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

STATUS OF THE CLAIMS

Claims 1 to 8 and 10 to 30 remain pending in the application. In Appellants' Amendment mailed January 2, 2001, Claims 1 and 25 were amended and Claim 9 was canceled. Appellants amended Claims 1 to 4, 7, 15, 25, 26, and 30 in an Amendment mailed August 3, 2001; amended Claims 1, 25, and 30 in an Amendment mailed July 24, 2002 and September 23, 2002; amended Claims 1, 25, and 30 in an Amendment mailed March 18, 2003; and amended Claims 1, 25, and 30 in an Amendment mailed August 28, 2003. All pending claims, a copy of which is attached hereto, are included in this appeal.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. 1.113, filed on August 28, 2003, was considered, but has been stated, in Advisory Action of September 12, 2003, as raising new issues that would require further consideration and/or search.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

SUMMARY OF THE INVENTION

The invention relates to a mascara composition comprising a plant extract component dispersed in a silicone oil. The plant extract can be dispersed in a volatile or non-volatile silicone oil. The plant extract contains its own natural plant fibers because it is processed from an unfiltered substantially whole fruit or vegetable. Thus, the extract of the present invention contains sticky sugary, gummy and tacky pulp as well as skin. The mascara compositions of the present invention containing the plant extract, however, are not tacky and produce longer, fuller, and natural looking lashes when applied thereto.

The cited reference fails to disclose or suggest that a seedless but otherwise substantially whole processed fruit or vegetable extract of the tacky constituents of the fruit or vegetable can be incorporated in a non-tacky mascara composition, and further it fails to disclose or suggest this extract dispersed in a silicone oil.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

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ISSUE

The outstanding issue is whether Claims 1 to 8, and 10 to 30 are anticipated by and rendered obvious by Pastour et al. (U.S. Pat. No. 5,523,091, hereinafter referred to as "the Pastour reference"), which discloses active principles such as plant extracts in the aqueous phase of a water-in-oil emulsion. The ordinary meaning of the term "plant extract" in the Pastour reference is not a disclosure or suggestion of the special meaning of the term "plant extract" in the present invention of an unfiltered substantially whole processed fruit or vegetable extract. Nor does the Pastour reference disclose or suggest a substantially whole fruit or vegetable extract dispersed in silicone oil.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

GROUPING OF CLAIMS

For purposes of determining patentability, Claims 1 to 8, and 10 to 30, drawn to the sole issue of the present appeal, are grouped together and all grounds of rejection which Appellants contest apply these claims. Claims 1, 10 to 14, 16 to 19, 21, 22, 24, and 25 are grouped together as they apply to the grounds of rejection based on 35 U.S.C. §102(b); and Claims 1 to 8, and 10 to 30 are grouped together as they apply to the grounds of rejection based on 35 U.S.C. §103(a).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

ARGUMENTS

1. The Examiner's Position on The Pastour Reference

With respect to the Examiner's rejection based on anticipation, the Pastour reference is cited by the Examiner for teaching compositions that can comprise active ingredients such as plant extracts between the amounts of 1 and 15 percent. The Pastour compositions are disclosed as cosmetic emulsions, and as importantly noted by the Examiner, can be in the form of a mascara. Further, as it pertains to the obviousness rejection, the Examiner admits that in Claims 2 and 3, the specific amounts of extract are not taught by the Pastour reference, and further, that the specific natural non-plant fiber claimed by Applicants is not taught by the Pastour reference. However, the Examiner asserts that the missing teaching of a natural non-plant fiber is overcome by the general teaching of inorganic and synthetic fillers. The lack of specific amounts in the Pastour reference are dismissed because it is the Examiner's position that one skilled in the art would modify the amount of active agent, depending on the specific needs of a particular formulation and further, that in the absence of unexpected results the slight difference between 0.5 percent and 1.0 percent is not a patentable distinction to the claims.

2. Appellant's Claimed Invention is Not Anticipated By The Pastour Reference

The subject matter of Claims 1, 10 to 14, 16 to 19, 21, 22, 24, and 25 are directed to a mascara composition comprising a seedless but otherwise substantially unfiltered whole processsed fruit or vegetable extract of at least tacky constituents from the fruit or vegetable wherein the tacky constituents are specifically pulp and/or skin dispersed in a silicone oil. The Pastour reference fails to disclose a composition containing tacky constituents from a fruit or vegetable extract nor does it disclose tacky constituents from a fruit or vegetable extract dispersed in a silicone oil. Without

sufficient clarity and detail in a cited reference, the subject matter of the claimed invention is not disclosed such that one of ordinary skill in the art would recognize its existence, and therefore, the claimed invention is not anticipated by the cited reference. *ATD Corp. v. Lydall Inc.*, 48 USPQ2d 1321, 1328 (CAFC 1988) (none of cited prior art references, disclosing multilayer insulation, anticipated claims for embossed insulating layers and compressed heat sink layers). The Pastour reference lacks sufficient clarity and detail in describing an active principle such as a plant extract to place in the possession of one skilled in the art the existence of the tacky constituents such as pulp or skin in a mascara composition. Further, the active principle disclosed by the Pastour reference is part of the aqueous phase and therefore, the Pastour reference similarly fails to provide clarity and detail in describing the fruit or vegetable extract of the present invention dispersed in a silicone oil. In addition, Claim 25 of the present invention describes a mascara composition comprising a plant extract dispersed in a volatile silicone oil, as well as an antistatic component, a non-plant fiber component, and a natural plant fiber component. The components of the present invention as described in Claim 25 are not disclosed by the Pastour reference.

a. Special Meaning of "Plant Extract" in Present Specification

At page 3, lines 24 to 32, the term "plant extract" is defined to have a special meaning such that the plant extract includes, except for the seeds, all of the constituents of the fruit of vegetable because they are not filtered. As recently supported by the decision in *Hockerson-Halberstadt Inc. v. Avia Group International Inc.*, 55 USPQ2d 1487, 1490 (CAFC 2000), although an ordinary meaning of a claim term is initially used as a default, the term may have a special meaning applied if the term is clearly defined in the specification because the patentee may act as a lexicographer and provide a different, or modified, meaning to the term. *Hockerson*, 55 USPQ2d at 1490 (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998) (observing that an applicant, acting as a lexicographer, may bestow "a special meaning to a term in order to convey a character or property or nuance relevant to the particular invention"); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388, 21 USPQ2d 1671, 1674 (Fed. Cir. 1994)). The nuance of the present invention is the substantially unfiltered plant extract whereby the whole pulp and skin of the plant are used in the compositions of the present invention. The Pastour reference does not disclose a plant extract of the present invention, namely, a seedless but substantially unfiltered extract containing pulp and skin, and therefore, the Pastour reference fails to disclose the present invention.

b. Ordinary Meaning of Plant Extract in Pastour Reference

The issue is: what is a "plant extract" as the term is used in the Pastour reference. Unlike the present specification, the Pastour reference is devoid of a special definition of a plant extract, and thus, the ordinary and accustomed meaning of the term applies to the use of the term "plant extract" in the Pastour reference. *Hockerson*, 55 USPQ2d at 1490. Evidence in the Pastour reference, and reference material indicates that the ordinary use of the term "plant extract" by one skilled in the art means a constituent separated from a whole plant containing a mixture of components. As mentioned in the present specification, at page 3, lines 28 to 30, contrary to the present invention, a plant extract is typically made by a separation procedure which removes the desired constituent from the whole plant. Consistent with this customary definition, an Analytical Chemistry Handbook, defines an "extraction" to be the process of selectively removing a solute, as for example an active principle, from a mixture with solvents, or the like. Dean, J. A., Analytical Chemistry Handbook, Chapter 2.2 Extraction Methods, pp. 2.15, McGraw-Hill (1995)(copy submitted herewith). In addition, the Webster's Encyclopedic Unabridged Dictionary of the English Language defines the noun "extract" to be a solution containing the active principles of a drug, plant juice, or the like, and to be a solid, viscid, a liquid substance extracted from a plant, drug, or the like. The verb "extract" means to separate or obtain (a juice, ingredient, principle, etc.) from a mixture by pressure, distillation, treatment with solvents or the like. Webster's Dictionary, Gramercy Books (1989) p. 505 (copy submitted herewith). As used at column 6, lines 3 to 7 of the Pastour reference, the "plant extract" is the source of the active principle which is extracted from a whole plant (i.e., the plant extract is separated from the whole plant to provide the active principle.)

Filtration is a specific extraction technique used to purify an extract and obtain the active principles contained therein. In support of this basic principle of analytical chemistry, a comment by Tibotec Pharmaceuticals, Ltd. ("Tibotec"), in response to an FDA guidance document, entitled Guidance for Industry Botanical Drug Products is illustrative. The comment substantiates that further purification of an extract yields an extract of the active principles. The disclosure in the Pastour reference of an active principle such as a plant extract is sufficient for one of ordinary skill in the art to understand the application of filtration to obtain the active principle. This is evidenced by section 2.3, *Purification* of the comment wherein it describes the final purification of an extract by filtration to produce the purified extract containing active compounds. Thus, it can be seen that

one of ordinary skill in the art knows and understands that a purified extract is produced by filtration and the end product is an extract containing active principles.

Next, Appellants refer to "l'Ami des ingrédients naturels", April 2001, Nr. 27, to further demonstrate the understanding that one of ordinary skill in the art would have about extracts. In the publication, cosmetic actives are defined to be molecules that are extracted from plants, and are not the same as the plants from which they are extracted. First, at page 1, of the l'Ami publication, it is explained that molecules that are extracted are called cosmetic actives. Further, at page 2 of this publication, it is noted that molecules are used as cosmetic active principles under the form of extracts. Finally, extraction techniques are, as described at page 3, of the l'Ami publication, designed to optimize the yield of the active material from the plant, and to obtain the active principle, yielded from the plant, in a stable and usable form. It is clear from this publication that one of ordinary skill in the art understands that the extract containing the active principle is obtained by extraction techniques applied to the plant and is not the plant, *per se*.

Appellants also provide examples of extracts defined by the Food and Drug Administration ("FDA") as flavorings, additives, and substances. In each example the extract is taken from a whole plant, fruit, vegetable, or the like. For example, at page 10, vanilla extract is an aqueous ethyl alcohol solution of the sapid and odorous principles extractable from vanilla beans. Indeed, vanilla extract is not vanilla beans, and a disclosure of vanilla extract is not a disclosure of vanilla beans. One of ordinary skill in the art readily understands that an ice-cream recipe disclosing vanilla extract and cream, *inter alia*, is not a disclosure of vanilla beans and cream. Anyone understands that the results will be different. One produces smooth and delicious vanilla ice cream and the other produces a frozen cream product with vanilla beans in it. According to the Examiner, because the Pastour reference discloses plant extracts, without a requirement for filtration, the Pastour reference also discloses the addition of vanilla beans to its compositions. First of all, this is a misrepresentation of the disclosure in the Pastour reference because the Pastour reference discloses active principles such as a plant extract. And, even if the Pastour reference disclosed plant extracts, *per se*, one of ordinary skill in the art would not, based on the Pastour reference, understand this to mean the substantially whole processed plant from which the extract is derived.

Finally, Appellants submit a press release by ExtractsPlus, January 15, 1998, as it is recognized therein that confusion over the definition of a botanical extract is the result of greater or lesser degree of accuracy exercised when using the term "plant extract." As an example, it is

stated in the press release that there "may be confusion between the pressed, dried juice of a plant and the extracts of the plant." In addition, the comment discusses the role of fillers in relation to extracts in section 5. Amount of filler in powdered extracts . . . Finally, but most importantly, this press release states,

> AN EXTRACT BY DEFINITION CANNOT CONTAIN ALL THE COMPONENTS OF THE RAW HERB.

Therefore, this press release and the other previously reviewed documents prove not only that the substantially whole processed extract of the present invention is not the plant extract of the Pastour reference as understood by one of ordinary skill in the art; but, that a requirement of filtration is inherent to the very essence of what an extract is and what it means to one of ordinary skill in the art, especially an extract used as the source of active principles.

The Pastour reference disclosure of an active principle such as a plant extract is of an active separated as an extract from a plant. Therefore, this is opposite in meaning from the plant extract of the present invention that has, except for the seeds, no part of the plant removed or separated from the extract. The constituents of the fruit or vegetable are not filtered. The whole pulp and skin of the fruit or vegetable are used. This is not disclosed by the Pastour reference.

c. Plant Extract of Present Invention is not Inherent in Pastour Reference

The Pastour reference fails to inherently disclose a substantially unfiltered plant extract. A prior art reference fails to anticipate if it does not disclose each and every element of the claimed invention, and if the missing element is not inherent in the prior art reference. *In re Robertson*, 49 USPQ2d 1949, 1951 (CAFC 1999)(citation omitted). To establish inherency, the extrinsic evidence "must make clear that the missing element is necessarily present in the subject matter described in the prior art reference, and that it would be recognized by those of ordinary skill in the art." *Id.* (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991)). Only the active principle, which albeit can be extracted from a plant, is used in the Pastour compositions, and one of ordinary skill in the art would recognize that the other constituents of the plant are not present in the Pastour extract. Further, the unfiltered plant extract would be expected by one of ordinary skill in the art to interfere with the activity of the desired active principle extracted from the plant, and the mixture of additional constituents from the whole plant would be expected to cause other qualitative disadvantages to the final

composition. Thus, the Pastour reference fails to disclose, expressly or inherently, the substantially unfiltered plant extract of the present invention. Based on the foregoing Applicants respectfully submit that the Pastour reference does not anticipate the present invention, and request that the Examiner's rejection under 35 U.S.C. §102(b) be withdrawn.

3. Appellant's Claimed Invention is Not Rendered Obvious By The Pastour Reference

In Claims 1 to 8, and 10 to 30, a mascara is described as containing a seedless but otherwise substantially unfiltered whole processed fruit or vegetable extract of at least the tacky constituents of the fruit or vegetable. Specifically, the tacky constituents include pulp and skin. The Pastour reference does not teach or suggest the plant extract of the present invention containing tacky constituents. The plant extract of the Pastour reference is achieved by a process of extraction whereby the desired constituent, i.e., the active principle, is separated from the undesired constituents. In the case of plants, and especially fruits and vegetables, some of the undesired constituents include pulp, skin, sugars, and other sticky and tacky compounds. These very sticky and tacky constituents are the plant extract of the present invention. The Pastour reference fails to teach or suggest the incorporation of the various constituents that exist in the unfiltered plant extract, and therefore, the present invention is unobvious in view of the Pastour reference.

Pursuant to §103, the question at issue is whether the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. 35 U.S.C. §103; *Perkin-Elmer Corp. v. Computervision Corp.*, 221 USPQ 669, 674 (CAFC 1984); see *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 1 USPQ2d 1241, 1246-47 (CAFC 1986); *Vandenberg. v. Dairy Equipment Co.*, 224 USPQ 195, 198 (CAFC 1984). This question is answered by viewing the claims of the invention in their entirety, not particular embodiments, to determine if the prior art references when combined teach or suggest the claimed subject matter to one of ordinary skill in the art. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303, 311 (CAFC 1983), cert. den., 469 U.S. 851 (1984); *Carl Schenck, A.G. v. Nortron Corp.*, 218 USPQ 698, 700 (CAFC 1983); *Jackson Jordan, Inc. v. Plasser American Corp.*, 224 USPQ 1, 9 (Fed. Cir. 1984) (noting *Graham v. John Deere Co.*, 148 USPQ 459, 467 (US SupCt 1966)); *In re Vaeck*, 20 USPQ2d 1438, 1442 (CA FC 1991); *In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976). In making an obviousness determination, the modification, and the nature and significance of the differences between the prior art and the claimed invention should be considered. Interim Guidelines for the

Examination of Claims Directed to Species of Chemical Compositions Based Upon a Single Prior Art Reference (hereinafter referred to as the "Interim Guidelines"), II.A.4.(c) Consider the Teachings of Structural Similarity.

The Pastour reference fails to teach or suggest a composition containing the unseparated plant extract of the present invention. The Pastour actives are separated from the plant extract. However, the present invention incorporates in its mascara compositions the unseparated plant extract. Typically, unfiltered natural ingredients contain sugars and starches that one of ordinary skill in the art would expect to make the mascara tacky. This is undesirable because the mascara is hard to apply and feels uncomfortable on the lashes. To remedy this problem, one known solution, as taught in the Pastour reference, is to separate individual components (e.g., actives) out of the plant extract that are desirable. It has not been taught or suggested in the Pastour reference, however, to use the whole unfiltered plant extract in its compositions, as in the compositions of the present invention. Because the Pastour reference does not teach or suggest a composition containing an unfiltered plant extract, this reference fails to render the present invention obvious.

a. Plant Extract of Claimed Invention is Surprising and Unexpected

In contrast to the Pastour reference, the present invention incorporates in its mascara compositions the unfiltered plant extract, and it is surprisingly not tacky. A *prima facie* case of obviousness can be overcome by "unexpected results," *i.e.*, showing that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the art would have found surprising or unexpected. *In re Soni*, 34 USPQ2d 1684, 1687 (CAFC 1995); *In re Piasecki*, 223 USPQ 785, 788 (CAFC 1984). In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (CAFC 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.*

The achievement of the present invention is surprising because one of ordinary skill in the art would expect an unfiltered plant extract in a mascara to be tacky. It is hard to apply a gummy mascara to the lashes. Once applied, the mascara is uncomfortable because it does not dry easily and because it can cause the upper and lower lashes to stick to one another, when it finally does dry. However, as provided in the present specification at page 8, lines 23 to 25, the mascara of the present invention surprisingly and unexpectedly performs the same as or better than conventional

mascaras. Further, as described in the present specification at page 4, lines 27 to 30, the unfiltered plant extract provides a natural fiber component to the mascara that enhances the thickness and length of the eyelashes.

As the Examiner has noted the mascara should be easy to apply, soft, uniform, and have good sensory qualities. Formulating a mascara with conventional synthetic ingredients to achieve these qualities is difficult enough. It is not expected that a mascara formula containing raw, substantially unfiltered fruits and vegetables would be able to achieve these qualities at all, nonetheless to perform comparably to conventional mascaras that are formulated to achieve these qualities with synthetically derived ingredients. Despite conventional wisdom, the mascara of the present invention containing unfiltered fruit extract (i.e., containing sticky sugar, gummy and tacky pulp and skin) is favorably compared with conventional mascaras that do not contain these ingredients and it is hard to reconcile how this could be anything but surprising. The Pastour reference, on the other hand, is no different than conventional mascaras. The ability of the mascara of the present invention to perform as well as traditional mascara is indeed unexpected because it contains nearly all of the components of the fruit or vegetable which would be expected to cause the mascara to perform poorly.

Therefore, Appellants submit the claims of the present application satisfy the requirements of 35 U.S.C. §103(a) because none of the cited references teaches or suggests a composition containing an unfiltered plant extract, and because the mascara is surprisingly and unexpectedly non-tacky. Thus, the Examiner has failed to establish a *prima facie* case of obviousness and Appellants request that the Examiner's rejection be withdrawn.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

CONCLUSION

In light of the data and the arguments presented above, the rejections of claims 1 to 8, and 10 to 30 based on anticipation and obviousness in view of the Pastour reference should be reversed as they are unfounded. The Pastour reference fails to disclose, teach or suggest a plant extract of the present invention that is an unfiltered whole processed fruit or vegetable extract of the tacky constituents of the fruit or vegetable. Accordingly, Appellants respectfully request that the Honorable Board reverse the decision of the Examiner finally rejecting the pending claims and declare that all pending claims in this application are allowable.

Respectfully submitted,

January 28, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

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APPENDIX: THE CLAIMS ON APPEAL

1.(currently amended) A mascara composition comprising a seedless but otherwise substantially unfiltered whole processed fruit or vegetable extract of at least tacky constituents of the fruit or vegetable selected from the group consisting of pulp and skin dispersed in a silicone oil.

2.(previously presented) The composition of claim 1 in which said whole processed fruit or vegetable extract is present in an amount of about 0.05 to about 0.50 percent by weight of the composition.

3.(previously presented) The composition of claim 2 in which said whole processed fruit or vegetable extract is present in an amount of about 0.1 to about 0.4 percent by weight of the composition.

4.(previously presented) The composition of claim 1 in which said whole processed fruit or vegetable extract is fruit-derived.

5.(original) The composition of claim 4 in which said fruit is selected from the group consisting of apple, pear, peach, mango, papaya, apricot, nectarine and combinations thereof.

6. (original) The composition of claim 5 in which said fruit is apple.

7.(previously presented) The composition of claim 1 in which said whole processed fruit or vegetable extract is vegetable-derived.

8.(original) The composition of claim 7 in which said vegetable is selected from the group consisting of yams, potatoes, peas, peppers, beans, squashes, carrots, and combinations thereof.

9.(canceled) The composition of claim 1 in which said extract is unfiltered.

10.(original) The composition of claim 1 in which said silicone oil is volatile.

11.(original) The composition of claim 10 in which said volatile oil is selected from the group consisting of cyclomethicone, hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane, and dimethylpolysiloxane.

12.(original) The composition of claim 11 in which said silicone oil is cyclomethicone.

13.(original) The composition of claim 1 in which said silicone oil is non-volatile.

14.(original) The composition of claim 13 in which said non-volatile oil is selected from the group consisting of dimethicone, cetyl dimethicone, phenyl trimethicone, lauryl trimethicone, dimethiconol, and mixtures thereof

15.(previously presented) The composition of claim 1 wherein said whole processed fruit or vegetable extract comprises natural fibers.

16.(original) The composition of claim 15 further comprising non-plant fibers selected from the group consisting of synthetic non-plant fibers and natural non-plant fibers.

17.(original) The composition of claim 16 in which said non-plant fiber is synthetic.

18.(original) The composition of claim 17 in which said synthetic fiber is selected from the group consisting of polyester, polyethylene, polypropylene, acrylic, aramid, rayon, cotton, wool, silk, nylon and blends fiber.

19.(original) The composition of claim 16 in which said non-plant fiber is natural.

20.(original) The composition of claim 19 in which said natural non-plant fiber is selected from the group consisting of chitin, etherified chitin, esterified chitin, chitosan, quaternary chitosan, and derivatives thereof.

21.(original) The composition of claim 16 further comprising an antistatic agent present in an amount of about 0.01 to about 10.00 percent by weight of the composition.

22. (original) The composition of claim 21 in which said antistatic component is selected from the group consisting of nonionic, anionic, cationic, and amphoteric surfactants; amino sugars; and mixtures thereof.

23. (original) The composition of claim 22 in which said amino sugar is chitin.

24. (original) The composition of claim 1 which also comprises a pigment.

25.(currently amended) A mascara composition comprising a seedless but otherwise substantially unfiltered whole processed fruit or vegetable extract of at least tacky constituents of the fruit or vegetable selected from the group consisting of pulp and skin dispersed in a volatile silicone oil, an antistatic component, a non-plant fiber component, and said whole processed fruit or vegetable extract comprising a natural fiber component.

26.(previously presented) The composition of claim 25 in which said whole processed fruit or vegetable extract is apple-derived.

27. (original) The composition of claim 26 in which said non-plant fiber component is nylon.

28.(original) The composition of claim 27 in which said antistatic component is chitin.

29.(original) The composition of claim 28 in which said non-plant fiber component further comprises chitin.

30.(currently amended) A mascara composition for application to the eyelashes comprising about 0.05 to about 0.50 percent by weight of the composition of a seedless but otherwise substantially unfiltered whole processed apple extract of at least tacky constituents of the fruit or vegetable selected from the group consisting of pulp and skin dispersed in a cyclomethicone, a non-plant fiber component comprising nylon and chitin, an antistatic component comprising chitin, and said whole processed apple extract comprising a natural apple fiber component.

Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, rm. 1061,
Rockville,
MD 20852

TIBOTEC

Tibotec Pharmaceuticals Ltd.
Blanchardstown Corporate Park
Blanchardstown, Dublin 15
Ireland
Tel. + 353 1 820 81 14
Fax + 353 1 820 80 82

Dublin, 8th December 2000

Dear Sir or Madam,

Re: Guidance for Industry, Botanical Drug Products – Comments
Docket No. 00D-1392, CDER 97113

On behalf of TIBOTEC, I wish to provide you with comments on the draft Guidance for Industry, Botanical Drug Products, of August 2000.

Introduction

TIBOTEC is an emerging, globally oriented pharmaceutical company, focused on discovering and developing superior pharmaceuticals for unmet medical needs. The scientific background of the company lies in the field of HIV infection and AIDS, infectious diseases (e.g. Leishmaniasis and tuberculosis), cancer and Alzheimer's disease.

TIBOTEC's headquarters and European R&D centre are located in Mechelen, Belgium. The US R&D laboratory, TIBOTEC, Inc., is located in Rockville, Maryland, USA. TIBOTEC's commercial activities are coordinated through TIBOTEC Pharmaceuticals Ltd., located in Dublin, Ireland. TIBOTEC Group NV was founded in 1994 by Rudi Pauwels, PhD, and Carine Claeys, pharmacist, with the objective of performing drug discovery and pre-clinical drug profiling in the focus areas. Paul Stoffels, MD, joined in 1997, when the target was extended to the establishment of an integrated pharmaceutical company. Dr. Pauwels authored the first paper describing the non-nucleoside HIV Reverse Transcriptase inhibitors (TIBO-compounds; *Nature 1990*).

TIBOTEC leverages intensive R&D efforts in AIDS drug discovery, resistance biology, and drug discovery technologies, such as ultra high-throughput screening, structure-based drug design and bio-informatics. The company has combined automation with intelligent image analysis methods to enable high-content screening of chemical libraries in cellular assays using a novel ultra high-throughput format. Drug discovery technologies, including structure-based drug design methods, are all aimed at increasing the speed and efficiency of target selection, assay design, and lead optimization.

Comments

In general, we are in agreement with the Guidance for Industry, Botanical Drug Products and we are pleased that such guidance is being drafted and will soon be available to industry.

00D-1392

I
C24

Nevertheless, we would like to express our concerns regarding the terms 'highly purified' and 'botanical drug substance' as used throughout the document. In the annex to these comments is an example of a purified botanical drug substance, upon which our concerns are based. In our opinion, this mixture should be considered as a botanical.

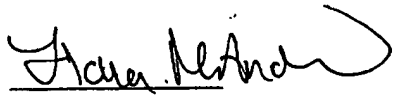
From the guidance, however, it is unclear given the level of purification as outlined in the annex, whether this botanical substance or mixture of substances is indeed considered a 'botanical'. More specifically, it is not clear if the unspecific term '.... or other similar process.' (as used in the sentence beginning 'It is prepared.....' In the definition for a Botanical Drug Substance) would apply to purification techniques such as those outlined in the example.

We therefore would like to see further clarification of the terms 'highly purified' and 'botanical drug substance' as used in this document with regard to specific stages and methods/techniques of processing.

We hope that the Centre for Drug Evaluation and Research will find these comments useful and consequently we hope to see them reflected in the final Guidance for Industry, Botanical Drug Products document.

Please contact me should you require more information or clarification.

Yours sincerely,



Fiona McAndrew
Regulatory Affairs Officer

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ANNEX

PURIFIED BOTANICAL DRUG (SUBSTANCE)

1. INTRODUCTION

The composition of a botanical drug may vary from very complex and poorly defined (an extract) to a (partially) defined purified extract using different purification techniques.
The product referred to in the comment document is a purified botanical drug obtained by the process described in more detail below.

2. PROCESS

Basically the production process consists of 3 steps:

- solid-liquid extraction of plant leaves
- liquid-liquid extraction and washing (purification)
- additional purification

The result of this process is a (partially) defined botanical extract.

2.1. Extraction

Dried and milled plant leaves are extracted with ethanol 70° by repeated maceration overnight and percolation, at a ratio plant material:alcohol of 1:5.

2.2. Initial purification

The ethanolic botanical extract is concentrated and purified by consecutive liquid-liquid extractions. These extractions facilitate the removal of lipid constituents (water//hexane) and water-soluble components (water/butanol). The semi-purified botanical extract is obtained by precipitation in aceton and washing with other organic solvents.

2.3. Purification

The final purification is performed using one or more different purification techniques.
Tannins are removed on a gel (Sephadex).
Filtration on a reversed phase packing possibly removes more polar and/or more lipophylic fractions.

Depending on the technique(s) used, a purified extract with a different composition can be obtained. The purified extract contains at least 6 identified active compounds and a matrix consisting of related compounds (unidentified but structurally related compounds) and other unknown compounds (such as inorganic salts).

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Sender's reference *first twelve characters will be shown on invoice*

4 Size and weight

No. of pieces: 1

Weight: .5 kg

Dimensions *cm L x W x H*

[illegible] PHARMACEUTICALS

[illegible]

[illegible] NCHARDSTOWN CORPORATE PARK

[illegible] ICHARDSTOWN DUBLIN 15

Postcode:

Phone / Fax / Telex: 353 1 8208114

2 To (Receiver)

Food + Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, rm 1061
Rockville, MD 20852

Postcode: 20852

USA

Contact person: Yuan-Yuan Chiu

Phone / Fax / Telex: 3018274573

3 Shipment details

Not all payment and service options are available in all countries.

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- [ ] OTHER SERVICE ..... *specify*

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- [ ] Transport Collect

Shipment insurance *see reverse*

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Full description of contents

Documents

International Worldwide Parcel Express shipments only

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Harmonised commodity code *if applies*:

Receiver's VAT / GST no. or EIN / SSN:

Type of export: [ ] PERMANENT [ ] REPAIR/RETURN [ ] TEMPORARY

Destination duties / taxes *If left blank receiver pays duties / taxes*

[ ] Receiver [ ] Sender [ ] Other ..... *Specify destination approved account number*

VOLUMETRIC/CHARGED WEIGHT: kg

CODES	CHARGES Services
	Special
	Insurance
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CURRENCY CODE	TOTAL

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Date: 11-12-00

5 Sender's authorisation and signature

We agree that DHL's standard terms apply to this shipment and limit DHL's liability. The Warsaw Convention may also apply (see reverse).

I/We understand that DHL does not transport cash or dangerous goods (see reverse)

Signature: Rhonda Keech

Date: 8/12/00

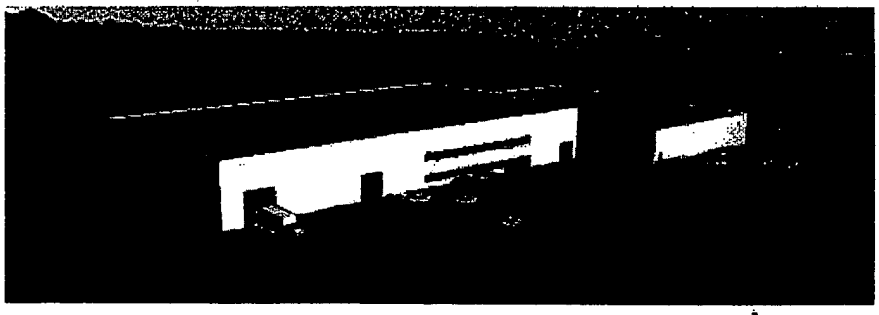
l'Ami

April 2001 • Nr 27 — des ingrédients naturels

Towards an ethics for development «natural»?

bringing substance capable of supporting the values of natural brands to the green label

We are pleased to announce the extension project of our manufacturing unit in Fontenay Sur Eure : Adonis. This new factory is dedicated to all of you, readers of l'AMI - who have made the choice of quality by Le Natural Product Designer®. This project is also a result of the still strong and growing vogue for natural products.



At the beginning of this new millennium, the panicking fear of the mad cow or genetically modified organisms even seem to add a further dimension to the «green wave». Is there only some agreement on the definition of the word natural?

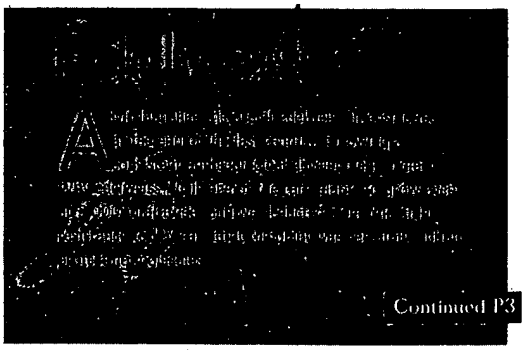
Is the chamomile extract in this shampoo the same chamomile shown on the packaging of this soothing cream? They have the same INCI name.... The wave may well be just... a wave precisely: rising and rolling on... nothing.

Would this all be but wind ? No. At least this is the answer we have been trying to substantiate since the first issues of l'AMI - it may even be the vocation of this news letter.

Continued P3

These molecules we extract

These molecules we extract and we call «cosmetic actives» are mostly generated by the secondary metabolism of plants (the primary one involving respiration and photosynthesis). In particular, they allow the adaptation of plants to their environment.



Continued P3

Adaptation to the environment

To cold

Plants of temperate climates adapt themselves to cold. Frost provokes ice crystals in cells, which damage their membranes and kill them. The most visible defence system to avoid this phenomenon is the loss of leaves in winter. Moreover, an accumulation of «antigel» molecules takes place in some plants (amino-acids, carbohydrates and derivatives) to lower the freezing point of the plant.

To aggression of parasites, predators, disease

Again, plants synthesize defensive and protective active molecules, mostly antibacterial and anti-fungal (particularly in essential oils) and even toxic to avoid consumption by animals.

To altitude

Further to the cold and dry conditions it generates, the mountain environment submits plants to another aggression: that of UV rays, the quantity of which increases by about 7 % each 300 m in altitude. This explains why plants rise in tiers on mountains. They become rarer and smaller with altitude. Besides these modifications visible to the bare eye, plants which resist to high altitude develop a protecting system of molecules able to screen out UV rays.

Continued P2

These molecules we extract (suite)

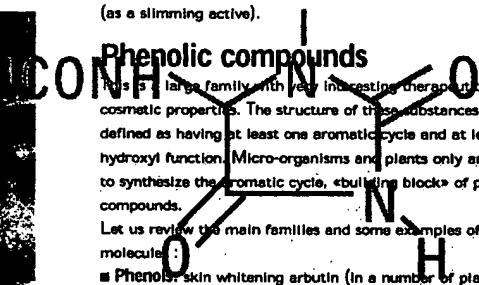
The large molecule families of the secondary metabolism

Terpenoids

They include phytohormones, numerous aromatic compounds particularly present in essential oils, the important carotenoid group, etc.

Alkaloids

They are often toxic molecules: curare, strychnine, cocaine. Caffeine is one of the rare alkaloids to be used in cosmetics (as a slimming active).



Phenolic compounds

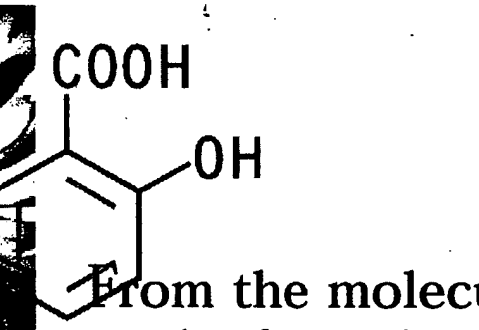
This is a large family with very interesting therapeutic and cosmetic properties. The structure of these substances can be defined as having at least one aromatic cycle and at least one hydroxyl function. Micro-organisms and plants only are able to synthesize the aromatic cycle, «building block» of phenolic compounds.

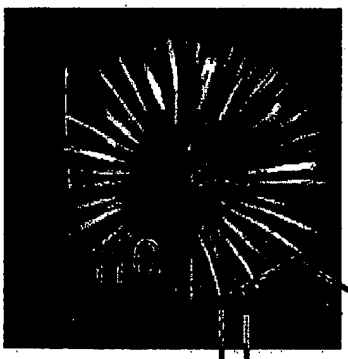
Let us review the main families and some examples of molecules:

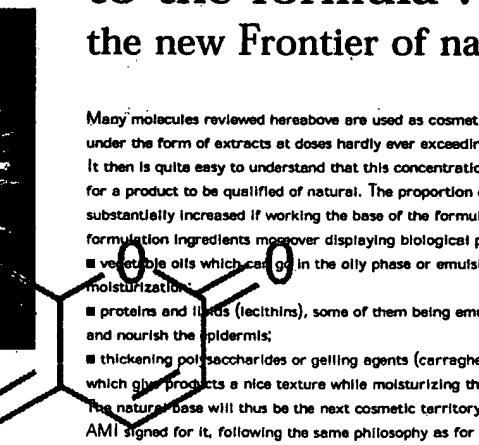
- **Phenols:** skin whitening arbutin (in a number of plants of the Ericaceae family, particularly bearberry).
- **Phenolic acids:** salicylic acid and its derivatives (in willow bark and meadowsweet) which have anti-inflammatory properties: they are at the origin of aspirin.
- **Tannins:** which combine to proteic molecules. Due to this property, they allow to «waterproof» the upper layers of the epidermis and protect the layers underneath.
- **Coumarins[1]:** there are about a thousand of them. Let us quote umbelliferone, present in particular in mouse-ear, and its bacteriostatic properties.
- **Flavonoids:** more than 3 000, they have a common biosynthetic origin. They are pigments widely spread in plants. Flavonoids are mainly known for their protecting activity on small blood vessels and their free radical scavenging properties (notably against the peroxidation of cell membrane lipids).

Some of them belong to the «collective unconscious» of the cosmetic industry: hyperoside of St John's wort, PCO of grape seeds, anthocyanins of red vine, soybean isoflavones, sylimarin of blessed thistle or gingketin of ginkgo.

1. Coumarins come from the vernacular name of the tonka bean: coumarou, from which coumarin was isolated in 1820.







From the molecule to the formula : the new Frontier of natural

Many molecules reviewed hereabove are used as cosmetic active principles under the form of extracts at doses hardly ever exceeding 0.5 %.

It then is quite easy to understand that this concentration shall not be enough for a product to be qualified of natural. The proportion of «natural» can be substantially increased if working the base of the formula with plant derived formulation ingredients moreover displaying biological properties:

- vegetable oils which can go in the oily phase or emulsions while improving moisturization;
- proteins and lipids (lecithins), some of them being emulsifying, which protect and nourish the epidermis;
- thickening polysaccharides or gelling agents (carragheenans, gums...) which give products a nice texture while moisturizing the skin.

The natural base will thus be the next cosmetic territory to investigate. AMI signed for it, following the same philosophy as for plant extracts: rigour and objectivity.

Our laboratories are at your disposal to go even further. So give your skin a new start for the third millenary with cosmetics made of all natural and active ingredients!

increase the proportion of natural in cosmetic products by working the formula up

«natural»?

Natural ? Maybe should we start with a definition of the word or at least to review the semantic territory it covers.

An ingredient is said «natural» when derived from vegetable resources, with high care not to damage its nature.

It is the case for herbal extracts, provided the extraction process respects the nature of the extracted molecules.

Historical source of skin care materials, natural products, traditionally ill-defined, have been slowly overtaken by scientific synthetic chemicals.

But this is not enough to dismiss their potential: powerful analytical techniques as well as modern agriculture provide the conditions for a rational renewal of natural skin care based on the numerous biologically active molecules synthesized by the plants. Viewed from the angle of vegetable chemistry, natural products may indeed satisfy the expectations of scientists as well as those of consumers: the vegetable molecule bridges the gap between the world of plant and the formulation laboratory, between the marketing story and efficacy.

the vegetable molecule bridges the gap between the world of plant and the formulation laboratory, between the marketing story and efficacity

If the industry has long questioned its members on the subject of myth and reality, the vegetable molecule, the missing link of cosmetics, is finally bringing the best of both world together.

The molecule perspective allows a complete organization of the natural supply chain:

- in order to optimize the yield in active materials of the plant, terms and conditions are precisely defined with producers;
- extraction techniques are designed to obtain the molecule in a stable and usable form;
- analytical methods are defined to guarantee the presence and the concentration of the molecule in the product;
- extracts are standardized for reproducible evaluation tests.

a lot of brands have engaged on a road of quality

All these guarantees condition the value and legitimacy of natural products. And it is on this validated ground that the natural label may authorize brands to write claims actually in relation to facts. Because they... deserve it !

It is true that when naturals become so important, many laboratories have decided to buy the label at the lowest cost: an INCI name is bought at the cheapest price. But the continuous growth of the Alban Muller Group also testifies that a lot of brands have engaged on the road to quality - looking for precisely defined products with reliable guarantees on the origin and the manufacturing process.

to seize the full meaning of naturals

The Alban Muller Group now offers product development assistance service in 45 countries.

Experts help you determine the technical parameters of you project - their laboratories and manufacturing units become yours to develop products adapted to your needs - but also adapted to the ethics of your brands : to seize the full meaning of naturals.

Meetings

Vitafoods

APRIL 24-26 • GENEVA • AMI VARISTOR

Catherine Douay catherine_douay@compuserve.com
Fabienne Kirchenbaum fabienne.kirchenbaum@albanmuller.com
Isabelle Nault isabelle.nault@albanmuller.com
Jean-Marc Seigneuret jmseig@albanmuller.com
Varistor info@vari-food.ch
Expect your visit at Palexpo - Booth 1512
1218 Le Grand-Saconnex - Geneva - Switzerland

In-cosmetics

APRIL 24-26 • DÜSSELDORF • AMI WORLEE

Adeline Courtier adeline.courtier@albanmuller.com
Ariane Csendes ariane.csendes@albanmuller.com
Armelle Magré amagre@albanmuller.com
Alban Muller the_boss@albanmuller.com
Worlee Mschwoy@ch.worlee.de
Expect your visit at Messe-Center - Booth 260
Hall 3 - Düsseldorf - Germany

X Congreso Nacional de la Química Cosmética

MAY 17-20 • IXTAPA ZIHUATANEJO • AMI ABA

«Nature and science at the service of the cosmetic industry»
Alban Muller the_boss@albanmuller.com
Reinhard Richter abe_ventas2@infosel.net.mx
Expect your visit on Alban Muller's lecture
at Meliá Azul Ixtapa Resort & Conference Center
Ixtapa Zihuatanejo - Mexico

SFC

JUNE 6-7 • PARIS

Alban Muller International expects your visit on the occasion of the 50th anniversary of the SFC at Palais des Congrès de Paris - Level 2 - Hall Maillot A
Contact Sophie Lemoine sophie.lemoine@albanmuller.com

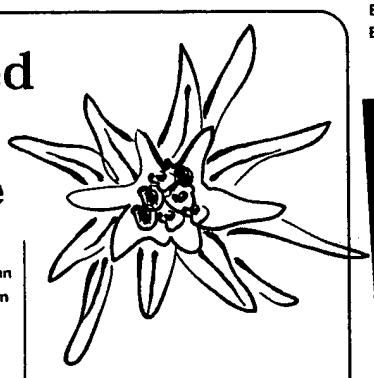
HBA

JULY 24-26 • SAO PAULO • AMI PIC

Alban Muller the_boss@albanmuller.com
The team PIC QUIMICA import@pic-quimica.com.br
Expect your visit at Expo Center Norte
Booth 150 - Sao Paulo - Brazil

Reasonable and integrated use of nature

Edelweiss : a successful example



Adaptation to altitude by an increased synthesis of polyphenols

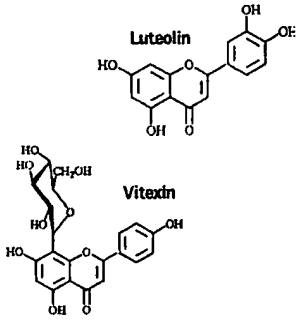
True mascot of the Alpine region and symbol of purity, edelweiss is a small annual plant with a fleecy aspect. What seems to be flowers are in fact the leaves disposed in a star shape and with a more fleecy aspect than the rest of the plant. The actual flowers are very small and not very decorative.

Edelweiss geographical origin is the Siberian steppes, where it resists to deep cold thanks to its downy and insulating coating made of thin hollow hairs.

Edelweiss grows mostly in rocky and sunny high mountain pastures, or calcareous rocks at an altitude of 800 to 3 000 m. It blossoms from June to September. It can grow in the snow, which gives it its image of purity and whiteness.

To be able to cope with such harsh climatic conditions, the plant must have adapted itself by a natural protective system not only against the cold, but also against U.V. rays which are particularly abundant at high altitudes. This physiological defence system consists in an efficient array of molecules resulting from the secondary metabolism with screening and antioxidant properties.The following molecules were put in evidence :

- flavonoids, particularly luteolin and apigenin and their glucosides : luteolin-7-glucoside and apigenin-7-glucoside, vitexin-2-rhamnoside ;
- phenolic acid of the cafeyl quinic type.



From an ecological point of view

Collecting edelweiss is submitted to regulations. We therefore set up a contract of integrated farming culture, within a programme of restoration of the Alpine sites.

Edelweiss: a cosmetic dream

From the German words edel, noble, and weiss, white, «edelweiss» itself evokes snowy summits, purity, original nature. In other words, it is an invitation to breathe the purest atmosphere thanks to extracts rich in protective molecules.

AMI offers in standard a watersoluble extract (propylene glycol) and an extract titrated in flavonoids (water and propylene glycol).

Alban Muller International
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Tel : 01 48 08 81 00 - Fax : 01 48 08 81 01
E-mail : info@albanmuller.com
Site web : www.albanmuller.com
Société Anonyme au capital de 40 000 €
RCS de Créteil numéro B 415 392 422
Président : Alban MULLER - Directeur Général : Laurent MULLER

L'AMI des Ingrédients Naturels

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Circulation: 17 000 copies in French and in English. L'AMI des Ingrédients Naturels can be sent to you upon request.

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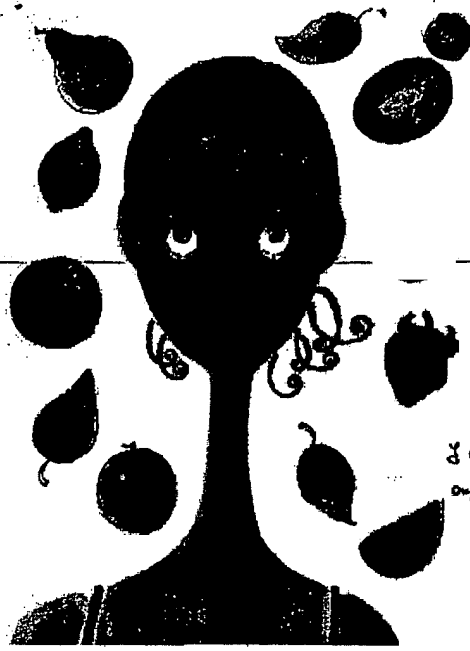

Regeneration : *millenium green*

According to the prophets, God created three realms that fill the three heavens. The first sphere, the love sphere, is red, the second sphere or sphere of wisdom is blue, the third sphere, sphere of creation, is green. Expressing soul regeneration, green also conveys the fecund union between water and earth. It stands for natural rebirth at ngtime, for renewal. It is the colour of youth, the colour of promises of a good arvest. Highly refreshing, gre means sap, vegetable blood, life bud. Green also stands for harmony and se ity. It soothes emotions, eases a tense atmosphere, stimulates respiratio and is an invitation to inner peace. It is a damp and lively colour, the colour of calm. Now then, why not come nd concoct new products? Come nd have a rest for a cosmetic picking of ens. To feel fresh as running wat frisky as young herbs, sparkling as young shoots. To get a good dose of energy an olour your cosmetics with sharp hints. AMI presents its Spring regenerating selection of rated extracts : watercress, fennel and cucumber with tonic, free-radical scavenging and oisturizing virtues.

If true beauty is a question of balance, I expect products to maintain and supplement the delicate mechanism of my skin

Free-radical scavenging fennel

Fennel has soothing, antiseptic, scrubbing, purifying and free radical scavenging properties. Fennel extracts can be used in body care products (scrubbing creams and gels), soothing care for the eye contour, face products for tired, sensitive and mature skin and also in hand products. The seed contains glucids (oses and osides), protids (16 to 20 % proteins), 17 to 20 % lipids, mineral matters (calcium, potassium), organic acids (citric, fumaric, malic, tartaric, ascorbic), phenolic compounds (phenolic acids -caffeic, ferulic, paracoumaric), flavonoids of the flavonol type (quercetine and kaempferol derivatives), coumarins, terpenoids (triterpenes and carotenoids), vitamins (B1, B2, B3, B5, B6), 2 to 6 % essential oil. AMI offers an extract titrated in phenolic compounds.

Foeniculum vulgare Mill.

Moisturizing cucumber

Cucumber has moisturizing and refreshing properties. It can be used in many cosmetic extracts, especially in face creams (dry and sensitive skin) and in after-sun products. The fresh pulp and the juice have soothing properties, they relieve skin and scalp irritations. Cucumber fruit contain osides (sucrose), protids among which amino acids (arginine) and enzymes (carboxylase, diastase), lipids, mineral matters (copper, iron, iodine, magnesium and zinc), organic acids (ascorbic acid), terpenoids (carotenoids), vitamins (thiamine, adenine). An extract titrated in proteins is available.

Cucumis sativus L.

Tonic watercress

Nasturtium officinale R. Br

Watercress has astringent, purifying, remineralizing and tonic activities. Watercress extracts are particularly appreciated in hair care products (for greasy hair, delicate and damaged hair) and against hair loss. They are also appreciated in body and mouth products. Lastly, watercress is a first choice ingredient in face care products for combination, oily and mature skin. Watercress contains sulphurated derivatives, mineral matters (calcium, iron, iodine, manganese and potassium), organic acids among which ascorbic acid, vitamins (retinol, carotenoids, thiamine, riboflavine and calciferol). The extract offered by AMI is titrated in flavonoids.

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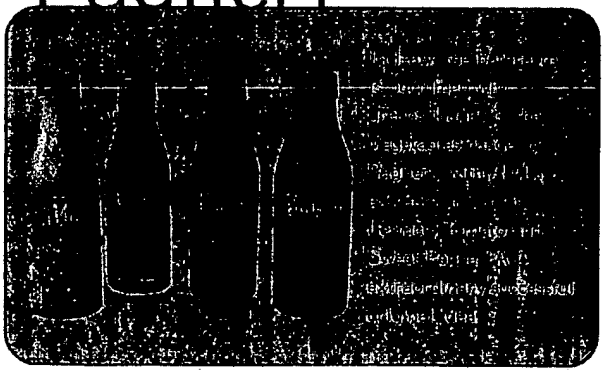

CONTACT : info@albanmuller.com

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION--

Subpart C--Solvents, Lubricants, Release Agents and Related Substances

Sec. 173.240 Isopropyl alcohol.

Isopropyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In lemon oil as a residue in production of the oil, at a level not to exceed 6 parts per million.

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(c) In hops **extract** as a residue from the extraction of hops at a level not to exceed 2.0 percent by weight: Provided, That,

(1) The hops **extract** is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops **extract** specifies the presence of the isopropyl alcohol and provides for the use of the hops **extract** only as prescribed by paragraph (c)(1) of this section.

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1262 Corn silk and corn silk extract.

(a) Corn silk is the fresh styles and stigmas of Zea mays L. collected when the corn is in milk. The filaments are extracted with dilute ethanol to produce corn silk extract. The extract may be concentrated at a temperature not exceeding 60 deg.C.

(b) The Food and Drug Administration, in cooperation with the National Academy of Sciences, is developing food-grade specifications for corn silk and corn silk extract. In the interim, this ingredient must be of a suitable purity for its intended use.

(c) In accordance with Sec. 184.1(b)(2), the ingredients are used in food only within the following specific limitations:

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Category of food	Maximum level of use in food (as served)\1\	Functional use
Baked goods and baking mixes, Sec. 170.3(n)(1) of this chapter.	30	Flavoring agent, Sec. 170.3(o)(12) of this chapter.
Nonalcoholic beverages, Sec. 170.3(n)(3) of this chapter.	20	Do.
Frozen dairy desserts, Sec. 170.3(n)(20) of this chapter.	10	Do.
Soft candy, Sec. 170.3(n)(38) of this chapter.	20	Do.
All other food categories.....	4	Do.

\1\ Parts per million.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29953, July 9, 1982]

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS--Table of

Subpart B--Food Additive Listing

Sec. 573.520 Hemicellulose **extract**.

Hemicellulose **extract** may be safely used in animal feed when incorporated therein in accordance with the following conditions:

(a) The additive is produced from the aqueous **extract** obtained by the treatment of wood with water at elevated temperatures (325 degrees-535 degrees F) and pressure (80 to 900 pounds per square inch) and contains primarily pentose and hexose sugars.

(b) The additive may be used in a liquid or dry state with the liquid product containing not less than 55 percent carbohydrate and the dry product containing not less than 84 percent carbohydrate.

(c) The additive is used as a source of metabolizable energy in animal feed in accordance with good manufacturing and feeding practices.

[41 FR 38652, Sept. 10, 1976, as amended at 43 FR 11181, Mar. 17, 1978]

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PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1445 Malt syrup (malt **extract**).

(a) Malt is the product of barley (Hordeum vulgare L.) germinated under controlled conditions. Malt syrup and malt **extract** are interchangeable terms for a viscous concentrate of water **extract** of germinated barley grain, with or without added safe preservative. Malt syrup is usually a brown, sweet, and viscous liquid containing varying amounts of amylolytic enzymes and plant constituents. Barley is first softened after cleaning by steeping operations and then allowed to germinate under controlled conditions. The germinated grain then undergoes processing, such as drying, grinding, extracting, filtering, and evaporating, to produce malt syrup (malt **extract**) with 75 to 80 percent solids or dried malt syrup with higher solids content.

(b) FDA is developing food-grade specifications for malt syrup (malt **extract**) in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in Sec. 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51613, Nov. 10, 1983]

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PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1560 Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008-63-7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.\1\

\1\ Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

(c) The ingredient is used as a surfactant as defined in Sec. 170.3(o)(29) of this chapter.

(d) The ingredient is used in food in accordance with Sec. 184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in Sec. 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 36064, Aug. 15, 1978. Redesignated and amended at 50 FR 49537, Dec. 3, 1985]

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTIO

Subpart F--Flavoring Agents and Related Substances

Sec. 172.580 Safrole-free **extract** of sassafras.

The food additive safrole-free **extract** of sassafras may be safely used in accordance with the following prescribed conditions:

(a) The additive is the aqueous **extract** obtained from the root bark of the plant Sassafras albidum (Nuttall) Nees (Fam. Lauraceae).

(b) It is obtained by extracting the bark with dilute alcohol, first concentrating the alcoholic solution by vacuum distillation, then diluting the concentrate with water and discarding the oily fraction.

(c) The purified aqueous **extract** is safrole-free.

(d) It is used as a flavoring in food.

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION--Table of Contents

Subpart A--Foods

Sec. 73.170 Grape skin **extract** (enocianina).

(a) Identity. (1) The color additive grape skin **extract** (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The **extract** is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin **extract** (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications. Grape skin **extract** (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.

(c) Uses and restrictions. Grape skin **extract** (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of parts 4 and 5, title 27 CFR.

(d) Labeling requirements. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of Sec. 70.25 of this chapter. The common or usual name of the color additive is ``grape skin **extract**'' followed, if desired, by ``(enocianina)''.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION--Table of Contents

Subpart A--Foods

Sec. 73.30 Annatto **extract**.

(a) Identity. (1) The color additive annatto **extract** is an **extract** prepared from annatto seed, Bixa orellana L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto **extract** may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) Specifications. Annatto **extract**, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto **extract** shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) Uses and restrictions. Annatto **extract** may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of Sec. 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of Sec. 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

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(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health and

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PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION--Table of Contents

Subpart A--Foods

Sec. 73.100 Cochineal **extract**; carmine.

(a) Identity. (1) The color additive cochineal **extract** is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic **extract** of cochineal (Dactylopius coccus costa (Coccus cacti L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (Dactylopius coccus costa (Coccus cacti L.)).

(3) Color additive mixtures for food use made with cochineal **extract** or carmine may contain only diluents that are suitable and that are listed in this

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subpart as safe in color additive mixtures for coloring foods.

(b) Specifications. (1) Cochineal **extract** shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25 deg.C.
Protein (N x 6.25), not more than 2.2 percent.
Total solids, not less than 5.7 and not more than 6.3 percent.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135 deg.C. for 3 hours), not more than 20.0 percent.
Ash, not more than 12.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0 percent.

Carmine and cochineal **extract** shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal **extract** free of viable Salmonella

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PART 169--FOOD DRESSINGS AND FLAVORINGS--Table of Contents

Subpart B--Requirements for Specific Standardized Food Dressings and Flavorings

Sec. 169.175 Vanilla extract.

(a) Vanilla extract is the solution in aqueous ethyl alcohol of the sapid and odorous principles extractable from vanilla beans. In vanilla extract the content of ethyl alcohol is not less than 35 percent by volume and the content of vanilla constituent, as defined in Sec. 169.3(c), is not less than one unit per gallon. The vanilla constituent may be extracted directly from vanilla beans or it may be added in the form of concentrated vanilla extract or concentrated vanilla flavoring or vanilla flavoring concentrated to the semisolid form called vanilla oleo-resin. Vanilla extract may contain one or more of the following optional ingredients:

(1) Glycerin.
(2) Propylene glycol.
(3) Sugar (including invert sugar).
(4) Dextrose.
(5) Corn sirup (including dried corn sirup).

(b)(1) The specified name of the food is ``Vanilla extract'' or ``Extract of vanilla''.

(2) When the vanilla extract is made in whole or in part by dilution of vanilla oleoresin, concentrated vanilla extract, or concentrated vanilla flavoring, the label shall bear the statement ``Made from _____'' or ``Made in part from _____'', the blank being filled in with the name or names ``vanilla oleoresin'', ``concentrated vanilla extract'', or ``concentrated vanilla flavoring'', as appropriate. If the article contains two or more units of vanilla constituent, the name of the food shall include the designation ``__-fold'', the blank being filled in with the whole

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number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

ExtractsPlus Recommends Guidelines for FDA Regulations in the Nutritional Supplement Industry

JAN. 21. 12:55AM

PRESS RELEASE

For Release, Immediately
Date: January 15,1998

For more information, call Staci Eisner, Technical Director
or Bill Roberts, President

Carlsbad, CA.-- The FDA's recent labeling rule has sparked heated discussion in the health supplement industry. This reaction led the FDA to invite industry input. ExtractsPlus, a distributor of botanical extracts, responded with specific recommendations. The main provisions of ExtractsPlus' petition can be summarized as follows:

1. Establish definitions for botanical extracts.

In order to implement rules for the labeling of botanical extracts, it is essential first to define what constitutes such an extract. There are a great variety of materials represented, with a greater or lesser degree of accuracy, as plant extracts. For example, there may be confusion between the pressed, dried juice of a plant and the extracts of the plant. Furthermore, the term "native extract" is often misunderstood. ExtractsPlus has proposed specific definitions for terms related to botanical extracts.

2. Establish a methodology to distinguish different types of extracts, without requiring confusing statements about the solvents used.

The FDA's latest ruling requires product labels to disclose the solvents used to make an extract, even when the solvents are removed to dryness. Extracts made from the same herb but using different solvents can have very different biochemical properties. For example, the beneficial fatty acids found in saw palmetto can only be extracted using special solvents which are chemically compatible with the fatty acids. For this reason, it is important for consumers to know how the extracts they buy were made Then if they are dissatisfied with the results obtained with one type of extract, they could switch to a different type.

Some members of the nutritional supplement industry are concerned that the practice of listing solvents may lead consumers to erroneously believe that significant solvent residues remain in the products. To avoid this confusion ExtractsPlus is proposing a system of solvent categorization. For example water-based extracts would be in one category, ethanol-based extracts in another, and so on. Product labels would list the category of solvent. The explicit naming of the solvent would be

unnecessary.

ExtractsPlus believes this scheme would help educate consumers to differentiate between products nominally containing the same herb. It would also assist marketers in creating brand distinction, and dosage form manufacturers in buying consistent raw materials.

3. The terms "extracts" and "raw herbs" should not be used interchangeably

Some manufacturers of health supplements use extracts as the "source" of an herb. For example, they might use 1 mg of a 50:1 extract and then label the product as containing 50 mg of herb. This sourcing is misleading to the consumer, and shows the great variance in potency of herbal supplements that may currently have the same information on their labels. An extract by definition cannot contain all the components of the raw herb. Therefore an extract should never be considered or used as the source of a plant for manufacturing purposes.

4. Plant:extract ratio notation should be clarified and disclosed.

The FDA's latest ruling defines a plant:extract ratio for use on the rebels of liquid extracts, but ignores any similar provision for powdered extracts. ExtractsPlus believes that this is a serious omission. Currently, there are several alternative ways to notate the plant:extract ratio. Let's say 4 kilos of herb are processed into 1 kilo of extract. The resulting powder could be described as a 4:1, a 1:4 or a 4x extract. When fillers are included in the computation of ratios, the issue is further complicated. The ratio confusion is exacerbated as it extends from the raw materials to the end product purchased by the buying public. ExtractsPlus recommends that the FDA establish standards for ratio notation used in labeling powdered extracts.

5. Amount of filler in powdered extracts should be taken into account

Even when plant:extract ratios are the same, the amount of filler used in powdered extracts can vary considerably. For example, a crude plant extract containing no filler would typically have a ratio of 5:1 and would contain a broad spectrum of the components naturally occurring in the plant. However, a 5:1 extract could also be manufactured by diluting a highly concentrated 100:1 extract with 95% filler. This latter extract would contain only a few of the plant's native principles. ExtractsPlus believes that it is important for consumers, formulators, and supplement manufacturers alike to discern the amount of filler. This can be handled either by excluding the amount of filler in the calculation of extract ratios, or explicitly stating the filler volume on product labels.

6. Supplement manufacturers, above all, need access to vital information.

Due to the complexity of the botanical extract market, it is difficult to formulate labeling guidelines which will accurately and universally convey each product's important qualities to the consumer. However, in order to ensure consistent quality, ExtractsPlus recommends that supplement manufacturers, at least, have access to all of this information, including:

- extraction solvent (type and concentration)

- plant:extract ratio, including ranges if applicable

- complete ingredient disclosure (including the type and concentration or range of concentration of any

and all excipients.)

This will enable dosage form manufacturers to accurately compare raw materials from different vendors and will thereby facilitate batch-to-batch consistency in products reaching the consumer.

Back

Webster's Encyclopedic Unabridged Dictionary of the English Language

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...ex-terior. 10. external features, ...ances, etc.; outward appearance; superficiali... *the externals of a religion attract the shallow and the ...minded.* [late ME; see EXTERN, -AL¹] —**ex-...ly,** *adv.*

...nal au/ditory mea/tus, *Anat.* the canal ...ing from the opening in the external ear to the ...mpanic membrane. See diag. under ear.

...nal-com-bus-tion (ik stûr/nᵊl kəm bus/...chən), *adj.* noting or pertaining to an engine, as a ...engine, in which fuel ignition takes place outside ...cylinder, turbine, or the like, in which heat energy is ...ansformed into mechanical force.

...nal ear/, the outer portion of the ear, con... of the auricle and the canal extending to the ...mpanic membrane. Cf. ear¹ (def. 1). See diag. under ...

...nal hem/orrhoid, *Pathol.* See under hem...

...nal il/iac ar/tery, *Anat.* See iliac artery.

...nal-i-za-tion (ik stûr/nᵊl ə zā/shən), *n. Chiefly ...* externalization.

...nal-ize (ik stûr/nᵊlīz/), *v.t.,* -ized, -iz-ing. ...rize externalize.

...nal-ism (ik stûr/nᵊlīz/əm), *n.* attention or ...to externals; excessive attention to externals, ...rtion. [EXTERNAL + -ISM] —**ex-ter/nal-ist,** *n.*

...nal-i-ty (ek/stər nal/i tē), *n., pl.* -ties. 1. ...e or quality of being external. 2. something ...an outward feature. 3. excessive attention ...als. [EXTERNAL + -ITY]

...nal-i-za-tion (ik stûr/nᵊlə zā/shən), *n.* 1. ...e process of externalizing. 2. the quality or ...being externalized. 3. that which is externalized. ...Brit., externalisation. [EXTERNALIZE + ...]

...nal-ize (ik stûr/nᵊlīz/), *v.t.,* -ized, -iz-ing. ...kes external; embody in an outward form: ...rs *externalizes the relational capacity of the ...tion.* 2. to regard as consisting of externals, ...gard or treat as being caused by externals; ...e to external causes: *to externalize one's difficul...* 3. to direct (the personality) outward in social ...ntips. Also, *esp. Brit.,* externalise. [EXTERNAL ...]

...nal jug/ular vein/. See under jugular ...

...nal rela/tion, *Philos.* a relation between ...entities such that if they had not been in this ...n to each other, the nature of each would not ...ssarily have been different. Cf. internal relation.

...o-cep-tive (ek/stər ə sep/tiv), *adj. Physiol.* ...ing to exteroceptors, the stimuli acting upon ...the nerve impulses initiated by them. [*exteroo-* form of L *exterus* EXTERIOR) + (RE)CEPTIVE]

...o-cep-tor (ek/stər ə sep/tər), *n. Physiol.* a ...r responding to stimuli originating from outside ...s. [*extero-* (see EXTEROCEPTIVE) + (RE)CEPTOR]

...ri-to-ri-al (ek/stə/tər i tôr/ē əl, -tōr/-), *adj.* ...torial. [EX-¹ + TERRITORIAL] —**ex-ter/ri-to/ri-al-ly,** *adv.* —**ex/ter-ri-to/ri-al-i-ty,** *n.*

...nct (ik stiŋkt/), *adj.* 1. not existing now; that ...ased or died out: *an extinct species of fish.* 2. ...er in use; obsolete: *an extinct custom.* 3. ex...nguished; quenched; not burning. 4. having ceased ...to be in force or active: *an extinct volcano.* [late ME *...xtinct(us)* put out, quenched, ptp. of *ex(s)tinguere* ...nguere] —**ex-tinct/ness,** *n.*

...nct gone, vanished. See dead. 2. archaic. 3, ...

...tion (ik stiŋk/shən), *n.* 1. the act of extin... 2. the fact or condition of being extinguished ...ct. 3. suppression; abolition: annihilation: ...ction of an army; *the extinction of hopes.* ...the act or process of becoming extinct; a coming ...ead or dying out: *the extinction of a species.* 5. ...the reduction or loss of a conditioned response ...ue to the absence or withdrawal of reinforce... [late ME *extinctio(n)* < L *ex(s)tinctiōn-* (s. of *ex(s)tinguere* ...nguere] —**ex-tinc/tion-al,** *adj.*

...tion me/ter, *Photog.* an exposure meter ...ing the intensity of light by the invisibility or ...faintness of one of a series of figures on a ...glass or sheet of celluloid of varying thickness.

...tive (ik stiŋk/tiv), *adj.* tending or serving ...guish. [EXTINCT + -IVE]

... (ek/stīn, -stin), *n. Bot.* exine. [< L *ext(imus)* ...tward + -INE²]

...guish (ik stiŋk/gwish), *v.t.* 1. to put out (a ..., etc.); put out the flame of (something ... or lighted): *to extinguish a candle.* 2. to put ...to or bring to an end; wipe out of existence: ...s: *to extinguish hope.* 3. to obscure or eclipse, ...superior brilliancy: *Her beauty extinguished that ...other women.* 4. *Law.* to discharge (a debt), ...payment. [< L *ex(s)tingu(ere)* (ex- EX-¹ + ...re to quench) + -ISH²] —**ex-tin/guish-a-ble,** ...ex-tin/guish-i-ble, *adj.* —**ex-tin/guish-ment,** *n.*

...guish-er (ik stiŋ/gwi shər), *n.* 1. one who ...e which extinguishes. 2. any of various portable ...es for extinguishing fire: *a chemical ex...* [EXTINGUISH + -ER¹]

...pate (ek/stər pāt/, ik stûr/pāt), *v.t.,* -pat-ed, ...ting. 1. to remove utterly; destroy totally; ...minate; do away with. 2. to pull up by or as if ...g roots; root up: *to extirpate a bad habit; to extirpate ...seeded hair.* [< L *ex(s)tirpāt(us)* plucked up ... stem (ptp. of *ex(s)tirpāre*), equiv. to *ex-* EX-¹ ... (s. of *stirps*) stem + *-ātus* -ATE¹] —**ex/tir-pa/tive,** *adj.* —**ex/tir-pa/tor,** *n.*

... (ik stōl/, -stol/), *v.t.,* -tolled, -tol-ling. to ...highly; laud; eulogize: *to extol the beauty of ...* Also, ex-tol/. [late ME *extolle(n)* < L *extollere* ...lift up, raise, equiv. to *ex-* EX-¹ + *tollere* to lift, ...up] —**ex-tol/ler,** *n.* —**ex-tol/ling-ly,** *adv.* —**ex-tol/ment,** *n.*

... commend, glorify, exalt, celebrate. —Ant. ...praise.

...tor-sive (ik stôr/siv), *adj. Law.* serving or tending ...extort: *extortive measures.* [< L *extort(us)* (ptp. of ...ortquere; see EXTORT) + -IVE] —**ex-tor/sive-ly,** *adv.*

...tort (ik stôrt/), *v.t.* 1. *Law.* a. to wrest or wring ...money, information, etc.) from a person by violence, intimidation, or abuse of authority; obtain by force, torture, threat, or the like. b. to take illegally or under color of office. 2. to compel (something) of a person by force: *Her charm and vivacity extorted their admiration.* [late ME (adj.) < L *extort(us)*, ptp. of *extorquēre*, equiv. to *ex-* EX-¹ + *torquēre* to twist] —**ex-tort/er,** *n.* —**ex-tor/tive,** *adj.* —**Syn.** 1. See extract.

ex-tor-tion (ik stôr/shən), *n.* 1. the act or an instance of extorting. 2. *Law.* the crime of obtaining money or some other thing of value under color of office, when none or not so much is due, or before it is due. 3. oppressive or illegal exaction, as of excessive price or interest: *the extortions of usurers.* 4. anything extorted. [ME *extorcion* < L *extortiōn-* (s. of *extortiō*). See EXTORT, -ION]

—Syn. 1, 4. blackmail.

ex-tor-tion-ar-y (ik stôr/shə ner/ē), *adj.* characterized by or given to extortion. [EXTORTION + -ARY]

ex-tor-tion-ate (ik stôr/shə nit), *adj.* 1. exorbitant; grossly excessive: *extortionate prices.* 2. characterized by extortion, as persons: *extortionate moneylenders.* [EXTORTION + -ATE¹] —**ex-tor/tion-ate-ly,** *adv.*

ex-tor-tion-er (ik stôr/shə nər), *n.* a person who practices extortion. Also, ex-tor/tion-ist. [ME *extorcioner*. See EXTORTION, -ER¹]

ex-tra (ek/strə), *adj.* 1. beyond or more than what is usual, expected, or necessary; additional: *an extra edition of a newspaper; an extra price.* 2. larger or better than what is usual: *an extra binding.* —*n.* 3. something extra or additional: *the little amenities and extras that make life pleasant.* 4. an additional expense. 5. an edition of a newspaper other than the regular edition or editions. 6. something of superior quality: *The Italian sports car was an extra.* 7. *Motion Pictures.* a person hired by the day to play a minor part as a member of a mob or crowd. 8. an additional worker: *The company hired several extras in order to finish the work on time.* 9. Usually, extras. *Cricket.* a score or run not made from the bat, as a bye or a wide. —*adv.* 10. in excess of the usual or specified amount: *an extra high price.* 11. beyond the ordinary degree; unusually; uncommonly: *done extra well; extra large.* [? by shortening of EXTRAORDINARY]

extra-, a prefix meaning "outside," "beyond," freely used as an English formative: *extrajudicial; extraterritorial; extra-atmospheric.* Also, extro-. [< L, comb. form of *extrā* (adv. and prep.) outside (of), without]

ex-tra-at-mos-pher-ic (ek/strə at/məs fer/ik), *adj.* outside the earth's atmosphere.

ex/tra-base/ hit/ (ek/strə bās/), *Baseball.* a base hit that enables a batter to reach more than one base safely, as a two-base hit, three-base hit, or home run.

ex-tra-bold (ek/strə bōld/), *Print.* —*n.* 1. unusually heavy boldface type. —*adj.* 2. in extrabold. [EXTRA- + BOLD]

ex-tra-ca-non-i-cal (ek/strə kə non/i kəl), *adj. Eccles.* not included in the canon of Scripture. [EXTRA- + CANONICAL]

ex-tra-cap-su-lar (ek/strə kap/sə lər), *adj.* outside a capsule or capsular thing. [EXTRA- + CAPSULAR]

ex-tra-cel-lu-lar (ek/strə sel/yə lər), *adj. Biol.* outside a cell or cells. [EXTRA- + CELLULAR] —**ex/tra-cel/lu-lar-ly,** *adv.*

ex-tra-con-densed (ek/strə kən denst/), *adj. Print.* (of type) narrower than condensed type in proportion to its height.

ex/tra cov/er, *Cricket.* 1. the position of a fielder between mid off and cover point. 2. the fielder occupying this position. Also, ex/tra cov/er point/.

ex-tract (*v.* ik strakt/; *n.* ek/strakt), *v.t.* 1. to get, pull, or draw out, usually with special effort or force: *to extract a tooth.* 2. to deduce (a doctrine, principle, interpretation, etc.): *He extracted a completely personal meaning from what was said.* 3. to derive or obtain (pleasure, comfort, etc.) from a particular source: *He extracted satisfaction from the success of his sons.* 4. to take or copy out (matter), as from a book. 5. to make excerpts from (a book, pamphlet, etc.). 6. to extort (information, money, etc.): *to extract a secret from someone.* 7. to separate or obtain (a juice, ingredient, principle, etc.) from a mixture by pressure, distillation, treatment with solvents, or the like. 8. *Math.* to determine (the root of a quantity). —*n.* 9. something extracted. 10. a passage taken from a book, article, etc.; excerpt; quotation. 11. a solution or preparation containing the active principles of a drug, plant juice, or the like; concentrated solution: *vanilla extract.* 12. a drug, or the like: *beef extract.* [late ME < L *extract(us)* (ptp. of *extrahere*). See EX-¹, TRACT¹] —**ex-tract/a-bil/i-ty,** *n.* —**ex-tract/a-ble, ex-tract/i-ble,** *adj.*

—Syn. 1. pry out. 6. evoke, educe, draw out, elicit. EXTRACT, EXACT, EXTORT, WREST imply using force to remove something. To EXTRACT is to draw forth something as by pulling, importuning, or the like: *to extract a confession by using third-degree methods.* To EXACT is to impose a penalty, or to obtain by force or authority, something to which one lays claim: *to exact payment, obedience.* To EXTORT is usually to wring something by intimidation or threats from an unwilling person: *to extort money by threats of blackmail.* To WREST is to take by force or violence in spite of active resistance: *The courageous minority wrested the power from their oppressors.* 7. withdraw, distill. 10. citation, selection. 11. decoction, distillation.

ex-tract-ant (ik strak/tənt), *n. Chem.* the substance extracted. [EXTRACT + -ANT]

ex-trac-tion (ik strak/shən), *n.* 1. the act or an instance of extracting. 2. the state or fact of being extracted: *In its extraction from the text the statement makes little sense.* 3. descent or lineage: *to be of foreign extraction.* 4. something extracted; extract. [late ME *extraccioun* < ML *extractiōn-* (s. of *extractiō*). See EXTRACT, -ION]

ex-trac-tive (ik strak/tiv), *adj.* 1. tending or serving to extract or based upon extraction: *the coal, oil, copper, and other extractive industries.* 2. capable of being extracted. 3. of or of the nature of an extract. —*n.* 4. something extracted. [EXTRACT + -IVE]

ex-trac-tor (ik strak/tər), *n.* 1. one who or that which extracts. 2. (in a firearm or cannon) the mechanism that, after firing, pulls an empty or unfired cartridge or shell case out of the chamber and brings it into place for action by the ejector. 3. a centrifuge for spinning wet laundry so as to remove excess water. 4. *Med., Dentistry,* an instrument for drawing out, extracting, or pulling. [EXTRACT + -OR²]

ex/tract print/ing. See discharge printing.

ex-tra-cur-ric-u-lar (ek/strə kə rik/yə lər), *adj.* 1. outside the regular curriculum: *extracurricular reading.* 2. of or pertaining to school activities exclusive of the regular academic course, as sports, singing in a glee club, etc. [EXTRA- + CURRICULAR]

ex-tra-dit-a-ble (ek/strə dī/tə bəl, ek/strə dī/-), *adj.* 1. capable of being extradited; subject to extradition: *an extraditable person.* 2. capable of incurring extradition: *an extraditable offense.* [EXTRADITE + -ABLE]

ex-tra-dite (ek/strə dīt/), *v.t.,* -dit-ed, -dit-ing. 1. to give up (a fugitive or prisoner) to another nation or authority. 2. to obtain the extradition of. [back formation from EXTRADITION]

ex-tra-di-tion (ek/strə dish/ən), *n.* the surrender of a fugitive from justice or a prisoner by one state or authority to another. [< F; see EX-¹, TRADITION]

ex/tra div/idend. See special dividend.

ex-tra-dos (ek/strə dos/, -dōs/, ek strā/dos, -dōs), *n., pl.* -dos (-dōs/, -dōz), -dos-es. *Archit.* the exterior curve or surface of an arch or vault. Also called back. Cf. intrados. See diag. under arch. [< F, equiv. to *extra-* EXTRA- + *dos* back (< L *dorsum* DORSUM)]

ex-tra-dosed (ek strā/dost), *adj.* (of an arch) having a curved intrados the form of which is repeated by the extrados. [EXTRADOS + -ED²]

ex-tra-em-bry-on-ic (ek/strə em/brē on/ik), *adj.* situated outside the body of the embryo; developed in connection with the embryo but not as a structural part of it. Also, ex/tra-em/bry-on/al. [EXTRA- + EMBRYONIC]

ex-tra-flo-ral (ek/strə flôr/əl, -flōr/-), *adj. Bot.* situated outside the flower, as a nectary. [EXTRA- + FLORAL]

ex-tra-ga-lac-tic (ek/strə gə lak/tik), *adj.* outside the Milky Way system: *an extragalactic nebula.* [EXTRA- + GALACTIC]

extragalac/tic neb/ula, *Astron.* nebula (def. 1c).

ex-tra-ju-di-cial (ek/strə jōō dish/əl), *adj.* 1. outside of judicial proceedings; beyond the action or authority of a court. 2. beyond, outside, or against the usual procedure of justice; legally unwarranted: *an extrajudicial penalty.* [EXTRA- + JUDICIAL] —**ex/tra-ju-di/cial-ly,** *adv.*

ex-tra-le-gal (ek/strə lē/gəl), *adj.* being beyond the province or authority of law. [EXTRA- + LEGAL] —**ex/tra-le/gal-ly,** *adv.*

ex-tra-mar-i-tal (ek/strə mar/i tᵊl), *adj.* pertaining to sexual relations with someone other than one's spouse. [EXTRA- + MARITAL]

ex-tra-met-ri-cal (ek/strə me/tri kəl), *adj. Pros.* containing one or more syllables in addition to those required by the meter: *an extrametrical line.* [EXTRA- + METRICAL]

ex-tra-mun-dane (ek/strə mun/dān, -mun dān/), *adj.* beyond our world or the material universe. [< LL *extrāmundān(us)* beyond the world. See EXTRA-, MUNDANE]

ex-tra-mu-ral (ek/strə myōōr/əl), *adj.* 1. involving representatives of more than one school: *extramural athletics.* 2. outside the walls or boundaries, as of a city or town or a university: *extramural teaching; an extramural church.* Cf. intramural (defs. 1, 2). [EXTRA- + MURAL] —**ex/tra-mu/ral-ly,** *adv.*

ex-tra-ne-ous (ik strā/nē əs), *adj.* 1. introduced or coming from without; not belonging or proper to a thing; external; foreign. 2. not pertinent; irrelevant: *an extraneous remark; extraneous decoration.* [< L *extrāneus* external, foreign, equiv. to *extr(a)-* EXTRA- + *-āneus* -ANEOUS] —**ex-tra/ne-ous-ly,** *adv.* —**ex-tra/ne-ous-ness,** *n.*

—Syn. 1. extrinsic, adventitious, alien. 2. inappropriate, nonessential, superfluous. —**Ant.** 1. intrinsic. 2. pertinent.

ex-tra-nu-cle-ar (ek/strə nōō/klē ər, -nyōō/-), *adj.* pertaining to or affecting the parts of a cell outside the nucleus. [EXTRA- + NUCLEAR]

ex-traor-di-nar-y (ik strôr/dᵊner/ē, ek/strə ôr/dᵊner/ē), *adj.* 1. beyond what is usual, ordinary, regular, or established: *extraordinary powers given to the President in wartime; unexpected extraordinary costs.* 2. exceptional in character, amount, extent, degree, etc.; noteworthy; remarkable: *extraordinary weather; extraordinary speed; an extraordinary man.* 3. (of an official, employee, etc.) outside of or additional to the ordinary staff; having a special, often temporary task or responsibility: *an extraordinary delegate to the Vatican.* [late ME *extraordinarie* < L *extraordinārī(us)* beyond what is ordinary. See EXTRA-, ORDINARY] —**ex-traor-di-nar-i-ly** (ik strôr/dᵊnâr/ə lē, ek/strə ôr/-), *adv.* —**ex-traor/di-nar/i-ness,** *n.*

—Syn. 1. inordinate. 2. uncommon, singular, rare, phenomenal, special, signal, egregious. —**Ant.** 1, 2. common, usual.

extraor/dinary ju/bilee. See under jubilee¹ (def. 5b).

extraor/dinary ray/, *Optics, Crystall.* the part of a doubly-refracted ray that has changed speed and vibrations in the principal plane of the crystal.

extraor/dinary wave/, *Radio.* (of the two waves into which a radio wave is divided in the ionosphere under the influence of the earth's magnetic field) the wave with characteristics more different from those that the undivided wave would have exhibited in the absence of the magnetic field. Also called X-wave. Cf. ordinary wave.

ex-tra-phys-i-cal (ek/strə fiz/i kəl), *adj.* outside the physical; not subject to physical laws. [EXTRA- + PHYSICAL]

ex-trap-o-late (ik strap/ə lāt/, ek/strə pə-), *v.,* -lat-ed, -lat-ing. —*v.t.* 1. *Statistics.* to estimate the value of a variable outside its tabulated or observed range. 2. to infer (that which is not known) from that which is known; conjecture. —*v.i.* 3. to perform extrapolation. [EXTRA- + (INTER)POLATE] —**ex-trap/o-la/tive,** *adj.* —**ex-trap/o-la/tion,** *n.* —**ex-trap/o-la-to-ry** (ik strap/ə lə tôr/ē, -tōr/ē), *adj.* —**ex-trap/o-la/tor,** *n.*

ANALYTICAL CHEMISTRY HANDBOOK

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Kinetic masking utilizes differences in rates f complex formation r dissociation. For example, ice-cold solutions at pH 2 of Ni-EDTA and Al-EDTA are only slowly dissociated by added Bi(III) ion, permitting Ni to be determined in the presence of Cd, Co, Cu(II), Mn(II), Pb, and Zn.

2.1.3 Demasking

For the major part, masking reactions that occur in solutions and lead to soluble compounds are equilibrium reactions. They usually require the use of an excess of the masking agent and can be reversed again by removal of the masking agent. The freeing of previously masked ionic or molecular species has been called *demasking*. This merits consideration in regard to its use in analysis. Masking never completely removes certain ionic or molecular species, but only reduces their concentrations. The extent of this lowering determines which color or precipitation reactions can be prevented. A system masked against a certain reagent is not necessarily masked against another but more aggressive reagent. It is therefore easy to see that masked reaction systems can also function as reagents at times (e.g., Fehling's solution, Nessler's reagent).

The methods used in demasking are varied. One approach is to change drastically the hydrogen ion concentration of the solution. The conditional stability constants of most metal complexes depend greatly on pH, so that simply raising or lowering the pH is frequently sufficient for selective demasking. In most cases a strong mineral acid is added, and the ligand is removed from the coordination sphere of the complex through the formation of a slightly ionized acid as with the polyprotic (citric, tartaric, EDTA, and nitriloacetic) acids.

Another type of demasking involves formation of new complexes or other compounds that are more stable than the masked species. For example, boric acid is used to demask fluoride complexes of tin(IV) and molybdenum(VI). Formaldehyde is often used to remove the masking action of cyanide ions by converting the masking agent to a nonreacting species through the reaction

$$CN^- + HCHO \rightleftharpoons OCH_2CN \qquad (2.19)$$

which forms glycollic nitrile. Pertinent instances are the demasking of $Ni(CN)_4^{2-}$ ions to Ni^{2+} ions by formaldehyde and the demasking of dimethylglyoxime (dmg) from $Pd(dmg)_2^{2-}$ ions by cyanide. Selectivity is evident in that $Zn(CN)_4^{2-}$ is demasked, whereas $Cu(CN)_3^{2-}$ is not.

Destruction of the masking ligand by chemical reaction may be possible, as in the oxidation of EDTA in acid solutions by permanganate or another strong oxidizing agent. Hydrogen peroxide and Cu(II) ion destroy the tartrate complex of aluminum.

Demasking methods for a number of masking agents are enumerated in Table 2.5.

2.2 EXTRACTION METHODS[11-13]

Most chemical reactions show poor selectivity as to the types of metal ions that take part. To improve the selectivity it is common to resort to extraction methods. Solutes have different solubilities in different solvents, and the process of selectively removing a solute from a mixture with a solvent is called *extraction*. The solute to be extracted may be in a solid or in a liquid medium, and the solvent used for the extraction process may be water, a water-miscible solvent, or a water-immiscible solvent. The selection of the solvent to be used depends upon the solute and upon the requirements of the experimental procedure. An ideal extraction method should be rapid, simple, and inexpensive to

[11] T. C. Lo, H. H. I. Baird, and C. Hanson, eds., *Handbook of Solvent Extraction*, Wiley-Interscience, New York, 1983.
[12] G. H. Morrison and H. Freiser, *Solvent Extraction in Analytical Chemistry*, Wiley, New York, 1957.
[13] J. Starý, *Metal Chelate Solvent Extraction*, Pergamon, Oxford, 1965.

Attorney Docket No.: 98.21US PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

APPELLANT'S BRIEF PURSUANT TO 37 CFR 1.191 AND 1.192

Assistant Commissioner of Patents and Trademarks

Attention: Board of Patent Appeals and Interferences

Washington, D.C. 20231

Dear Sir:

Applicants hereby appeal to the Board of Patent Appeals and Interferences from the final rejection of claims 1 to 8, and 10 to 30 in the present application in the decision of May 28, 2003.

Attorney Docket No.: 98.21US PATENT

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REAL PARTY IN INTEREST

The name of the real party in interest in this appeal is Color Access, Inc., the assignee of the application.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences relating to the instant application that would directly affect, be directly affected by, or have a bearing of any kind on the Board's decision in this appeal that are known to Appellants.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

STATUS OF THE CLAIMS

Claims 1 to 8 and 10 to 30 remain pending in the application. In Appellants' Amendment mailed January 2, 2001, Claims 1 and 25 were amended and Claim 9 was canceled. Appellants amended Claims 1 to 4, 7, 15, 25, 26, and 30 in an Amendment mailed August 3, 2001; amended Claims 1, 25, and 30 in an Amendment mailed July 24, 2002 and September 23, 2002; amended Claims 1, 25, and 30 in an Amendment mailed March 18, 2003; and amended Claims 1, 25, and 30 in an Amendment mailed August 28, 2003. All pending claims, a copy of which is attached hereto, are included in this appeal.

Attorney Docket No.: 98.21US PATENT

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STATUS OF AMENDMENTS

An Amendment under 37 C.F.R. 1.113, filed on August 28, 2003, was considered, but has been stated, in Advisory Action of September 12, 2003, as raising new issues that would require further consideration and/or search.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

SUMMARY OF THE INVENTION

The invention relates to a mascara composition comprising a plant extract component dispersed in a silicone oil. The plant extract can be dispersed in a volatile or non-volatile silicone oil. The plant extract contains its own natural plant fibers because it is processed from an unfiltered substantially whole fruit or vegetable. Thus, the extract of the present invention contains sticky sugary, gummy and tacky pulp as well as skin. The mascara compositions of the present invention containing the plant extract, however, are not tacky and produce longer, fuller, and natural looking lashes when applied thereto.

The cited reference fails to disclose or suggest that a seedless but otherwise substantially whole processed fruit or vegetable extract of the tacky constituents of the fruit or vegetable can be incorporated in a non-tacky mascara composition, and further it fails to disclose or suggest this extract dispersed in a silicone oil.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

ISSUE

The outstanding issue is whether Claims 1 to 8, and 10 to 30 are anticipated by and rendered obvious by Pastour et al. (U.S. Pat. No. 5,523,091, hereinafter referred to as "the Pastour reference"), which discloses active principles such as plant extracts in the aqueous phase of a water-in-oil emulsion. The ordinary meaning of the term "plant extract" in the Pastour reference is not a disclosure or suggestion of the special meaning of the term "plant extract" in the present invention of an unfiltered substantially whole processed fruit or vegetable extract. Nor does the Pastour reference disclose or suggest a substantially whole fruit or vegetable extract dispersed in silicone oil.

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GROUPING OF CLAIMS

For purposes of determining patentability, Claims 1 to 8, and 10 to 30, drawn to the sole issue of the present appeal, are grouped together and all grounds of rejection which Appellants contest apply these claims. Claims 1, 10 to 14, 16 to 19, 21, 22, 24, and 25 are grouped together as they apply to the grounds of rejection based on 35 U.S.C. §102(b); and Claims 1 to 8, and 10 to 30 are grouped together as they apply to the grounds of rejection based on 35 U.S.C. §103(a).

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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ARGUMENTS

1. The Examiner's Position on The Pastour Reference

With respect to the Examiner's rejection based on anticipation, the Pastour reference is cited by the Examiner for teaching compositions that can comprise active ingredients such as plant extracts between the amounts of 1 and 15 percent. The Pastour compositions are disclosed as cosmetic emulsions, and as importantly noted by the Examiner, can be in the form of a mascara. Further, as it pertains to the obviousness rejection, the Examiner admits that in Claims 2 and 3, the specific amounts of extract are not taught by the Pastour reference, and further, that the specific natural non-plant fiber claimed by Applicants is not taught by the Pastour reference. However, the Examiner asserts that the missing teaching of a natural non-plant fiber is overcome by the general teaching of inorganic and synthetic fillers. The lack of specific amounts in the Pastour reference are dismissed because it is the Examiner's position that one skilled in the art would modify the amount of active agent, depending on the specific needs of a particular formulation and further, that in the absence of unexpected results the slight difference between 0.5 percent and 1.0 percent is not a patentable distinction to the claims.

2. Appellant's Claimed Invention is Not Anticipated By The Pastour Reference

The subject matter of Claims 1, 10 to 14, 16 to 19, 21, 22, 24, and 25 are directed to a mascara composition comprising a seedless but otherwise substantially unfiltered whole processsed fruit or vegetable extract of at least tacky constituents from the fruit or vegetable wherein the tacky constituents are specifically pulp and/or skin dispersed in a silicone oil. The Pastour reference fails to disclose a composition containing tacky constituents from a fruit or vegetable extract nor does it disclose tacky constituents from a fruit or vegetable extract dispersed in a silicone oil. Without

sufficient clarity and detail in a cited reference, the subject matter of the claimed invention is not disclosed such that one of ordinary skill in the art would recognize its existence, and therefore, the claimed invention is not anticipated by the cited reference. *ATD Corp. v. Lydall Inc.*, 48 USPQ2d 1321, 1328 (CAFC 1988) (none of cited prior art references, disclosing multilayer insulation, anticipated claims for embossed insulating layers and compressed heat sink layers). The Pastour reference lacks sufficient clarity and detail in describing an active principle such as a plant extract to place in the possession of one skilled in the art the existence of the tacky constituents such as pulp or skin in a mascara composition. Further, the active principle disclosed by the Pastour reference is part of the aqueous phase and therefore, the Pastour reference similarly fails to provide clarity and detail in describing the fruit or vegetable extract of the present invention dispersed in a silicone oil. In addition, Claim 25 of the present invention describes a mascara composition comprising a plant extract dispersed in a volatile silicone oil, as well as an antistatic component, a non-plant fiber component, and a natural plant fiber component. The components of the present invention as described in Claim 25 are not disclosed by the Pastour reference.

a. Special Meaning of "Plant Extract" in Present Specification

At page 3, lines 24 to 32, the term "plant extract" is defined to have a special meaning such that the plant extract includes, except for the seeds, all of the constituents of the fruit of vegetable because they are not filtered. As recently supported by the decision in *Hockerson-Halberstadt Inc. v. Avia Group International Inc.*, 55 USPQ2d 1487, 1490 (CAFC 2000), although an ordinary meaning of a claim term is initially used as a default, the term may have a special meaning applied if the term is clearly defined in the specification because the patentee may act as a lexicographer and provide a different, or modified, meaning to the term. *Hockerson*, 55 USPQ2d at 1490 (citing *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998) (observing that an applicant, acting as a lexicographer, may bestow "a special meaning to a term in order to convey a character or property or nuance relevant to the particular invention"); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1388, 21 USPQ2d 1671, 1674 (Fed. Cir. 1994)). The nuance of the present invention is the substantially unfiltered plant extract whereby the whole pulp and skin of the plant are used in the compositions of the present invention. The Pastour reference does not disclose a plant extract of the present invention, namely, a seedless but substantially unfiltered extract containing pulp and skin, and therefore, the Pastour reference fails to disclose the present invention.

b. Ordinary Meaning of Plant Extract in Pastour Reference

The issue is: what is a "plant extract" as the term is used in the Pastour reference. Unlike the present specification, the Pastour reference is devoid of a special definition of a plant extract, and thus, the ordinary and accustomed meaning of the term applies to the use of the term "plant extract" in the Pastour reference. *Hockerson*, 55 USPQ2d at 1490. Evidence in the Pastour reference, and reference material indicates that the ordinary use of the term "plant extract" by one skilled in the art means a constituent separated from a whole plant containing a mixture of components. As mentioned in the present specification, at page 3, lines 28 to 30, contrary to the present invention, a plant extract is typically made by a separation procedure which removes the desired constituent from the whole plant. Consistent with this customary definition, an Analytical Chemistry Handbook, defines an "extraction" to be the process of selectively removing a solute, as for example an active principle, from a mixture with solvents, or the like. Dean, J. A., Analytical Chemistry Handbook, Chapter 2.2 Extraction Methods, pp. 2.15, McGraw-Hill (1995)(copy submitted herewith). In addition, the Webster's Encyclopedic Unabridged Dictionary of the English Language defines the noun "extract" to be a solution containing the active principles of a drug, plant juice, or the like, and to be a solid, viscid, a liquid substance extracted from a plant, drug, or the like. The verb "extract" means to separate or obtain (a juice, ingredient, principle, etc.) from a mixture by pressure, distillation, treatment with solvents or the like. Webster's Dictionary, Gramercy Books (1989) p. 505 (copy submitted herewith). As used at column 6, lines 3 to 7 of the Pastour reference, the "plant extract" is the source of the active principle which is extracted from a whole plant (i.e., the plant extract is separated from the whole plant to provide the active principle.)

Filtration is a specific extraction technique used to purify an extract and obtain the active principles contained therein. In support of this basic principle of analytical chemistry, a comment by Tibotec Pharmaceuticals, Ltd. ("Tibotec"), in response to an FDA guidance document, entitled Guidance for Industry Botanical Drug Products is illustrative. The comment substantiates that further purification of an extract yields an extract of the active principles. The disclosure in the Pastour reference of an active principle such as a plant extract is sufficient for one of ordinary skill in the art to understand the application of filtration to obtain the active principle. This is evidenced by section 2.3, *Purification* of the comment wherein it describes the final purification of an extract by filtration to produce the purified extract containing active compounds. Thus, it can be seen that

one of ordinary skill in the art knows and understands that a purified extract is produced by filtration and the end product is an extract containing active principles.

Next, Appellants refer to "l'Ami des ingrédients naturels", April 2001, Nr. 27, to further demonstrate the understanding that one of ordinary skill in the art would have about extracts. In the publication, cosmetic actives are defined to be molecules that are extracted from plants, and are not the same as the plants from which they are extracted. First, at page 1, of the l'Ami publication, it is explained that molecules that are extracted are called cosmetic actives. Further, at page 2 of this publication, it is noted that molecules are used as cosmetic active principles under the form of extracts. Finally, extraction techniques are, as described at page 3, of the l'Ami publication, designed to optimize the yield of the active material from the plant, and to obtain the active principle, yielded from the plant, in a stable and usable form. It is clear from this publication that one of ordinary skill in the art understands that the extract containing the active principle is obtained by extraction techniques applied to the plant and is not the plant, *per se*.

Appellants also provide examples of extracts defined by the Food and Drug Administration ("FDA") as flavorings, additives, and substances. In each example the extract is taken from a whole plant, fruit, vegetable, or the like. For example, at page 10, vanilla extract is an aqueous ethyl alcohol solution of the sapid and odorous principles extractable from vanilla beans. Indeed, vanilla extract is not vanilla beans, and a disclosure of vanilla extract is not a disclosure of vanilla beans. One of ordinary skill in the art readily understands that an ice-cream recipe disclosing vanilla extract and cream, *inter alia*, is not a disclosure of vanilla beans and cream. Anyone understands that the results will be different. One produces smooth and delicious vanilla ice cream and the other produces a frozen cream product with vanilla beans in it. According to the Examiner, because the Pastour reference discloses plant extracts, without a requirement for filtration, the Pastour reference also discloses the addition of vanilla beans to its compositions. First of all, this is a misrepresentation of the disclosure in the Pastour reference because the Pastour reference discloses active principles such as a plant extract. And, even if the Pastour reference disclosed plant extracts, *per se*, one of ordinary skill in the art would not, based on the Pastour reference, understand this to mean the substantially whole processed plant from which the extract is derived.

Finally, Appellants submit a press release by ExtractsPlus, January 15, 1998, as it is recognized therein that confusion over the definition of a botanical extract is the result of greater or lesser degree of accuracy exercised when using the term "plant extract." As an example, it is

stated in the press release that there "may be confusion between the pressed, dried juice of a plant and the extracts of the plant." In addition, the comment discusses the role of fillers in relation to extracts in section 5. Amount of filler in powdered extracts . . . Finally, but most importantly, this press release states,

> AN EXTRACT BY DEFINITION CANNOT CONTAIN ALL THE COMPONENTS OF THE RAW HERB.

Therefore, this press release and the other previously reviewed documents prove not only that the substantially whole processed extract of the present invention is not the plant extract of the Pastour reference as understood by one of ordinary skill in the art; but, that a requirement of filtration is inherent to the very essence of what an extract is and what it means to one of ordinary skill in the art, especially an extract used as the source of active principles.

The Pastour reference disclosure of an active principle such as a plant extract is of an active separated as an extract from a plant. Therefore, this is opposite in meaning from the plant extract of the present invention that has, except for the seeds, no part of the plant removed or separated from the extract. The constituents of the fruit or vegetable are not filtered. The whole pulp and skin of the fruit or vegetable are used. This is not disclosed by the Pastour reference.

c. Plant Extract of Present Invention is not Inherent in Pastour Reference

The Pastour reference fails to inherently disclose a substantially unfiltered plant extract. A prior art reference fails to anticipate if it does not disclose each and every element of the claimed invention, and if the missing element is not inherent in the prior art reference. *In re Robertson*, 49 USPQ2d 1949, 1951 (CAFC 1999)(citation omitted). To establish inherency, the extrinsic evidence "must make clear that the missing element is necessarily present in the subject matter described in the prior art reference, and that it would be recognized by those of ordinary skill in the art." *Id.* (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991)). Only the active principle, which albeit can be extracted from a plant, is used in the Pastour compositions, and one of ordinary skill in the art would recognize that the other constituents of the plant are not present in the Pastour extract. Further, the unfiltered plant extract would be expected by one of ordinary skill in the art to interfere with the activity of the desired active principle extracted from the plant, and the mixture of additional constituents from the whole plant would be expected to cause other qualitative disadvantages to the final

composition. Thus, the Pastour reference fails to disclose, expressly or inherently, the substantially unfiltered plant extract of the present invention. Based on the foregoing Applicants respectfully submit that the Pastour reference does not anticipate the present invention, and request that the Examiner's rejection under 35 U.S.C. §102(b) be withdrawn.

3. Appellant's Claimed Invention is Not Rendered Obvious By The Pastour Reference

In Claims 1 to 8, and 10 to 30, a mascara is described as containing a seedless but otherwise substantially unfiltered whole processed fruit or vegetable extract of at least the tacky constituents of the fruit or vegetable. Specifically, the tacky constituents include pulp and skin. The Pastour reference does not teach or suggest the plant extract of the present invention containing tacky constituents. The plant extract of the Pastour reference is achieved by a process of extraction whereby the desired constituent, i.e., the active principle, is separated from the undesired constituents. In the case of plants, and especially fruits and vegetables, some of the undesired constituents include pulp, skin, sugars, and other sticky and tacky compounds. These very sticky and tacky constituents are the plant extract of the present invention. The Pastour reference fails to teach or suggest the incorporation of the various constituents that exist in the unfiltered plant extract, and therefore, the present invention is unobvious in view of the Pastour reference.

Pursuant to §103, the question at issue is whether the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. 35 U.S.C. §103; *Perkin-Elmer Corp. v. Computervision Corp.*, 221 USPQ 669, 674 (CAFC 1984); see *Akzo N.V. v. U.S. Int'l Trade Comm'n*, 1 USPQ2d 1241, 1246-47 (CAFC 1986); *Vandenberg. v. Dairy Equipment Co.*, 224 USPQ 195, 198 (CAFC 1984). This question is answered by viewing the claims of the invention in their entirety, not particular embodiments, to determine if the prior art references when combined teach or suggest the claimed subject matter to one of ordinary skill in the art. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 USPQ 303, 311 (CAFC 1983), cert. den., 469 U.S. 851 (1984); *Carl Schenck, A.G. v. Nortron Corp.*, 218 USPQ 698, 700 (CAFC 1983); *Jackson Jordan, Inc. v. Plasser American Corp.*, 224 USPQ 1, 9 (Fed. Cir. 1984) (noting *Graham v. John Deere Co.*, 148 USPQ 459, 467 (US SupCt 1966)); *In re Vaeck*, 20 USPQ2d 1438, 1442 (CA FC 1991); *In re Rinehart*, 189 USPQ 143, 147 (CCPA 1976). In making an obviousness determination, the modification, and the nature and significance of the differences between the prior art and the claimed invention should be considered. Interim Guidelines for the

Examination of Claims Directed to Species of Chemical Compositions Based Upon a Single Prior Art Reference (hereinafter referred to as the "Interim Guidelines"), II.A.4.(c) Consider the Teachings of Structural Similarity.

The Pastour reference fails to teach or suggest a composition containing the unseparated plant extract of the present invention. The Pastour actives are separated from the plant extract. However, the present invention incorporates in its mascara compositions the unseparated plant extract. Typically, unfiltered natural ingredients contain sugars and starches that one of ordinary skill in the art would expect to make the mascara tacky. This is undesirable because the mascara is hard to apply and feels uncomfortable on the lashes. To remedy this problem, one known solution, as taught in the Pastour reference, is to separate individual components (e.g., actives) out of the plant extract that are desirable. It has not been taught or suggested in the Pastour reference, however, to use the whole unfiltered plant extract in its compositions, as in the compositions of the present invention. Because the Pastour reference does not teach or suggest a composition containing an unfiltered plant extract, this reference fails to render the present invention obvious.

a. Plant Extract of Claimed Invention is Surprising and Unexpected

In contrast to the Pastour reference, the present invention incorporates in its mascara compositions the unfiltered plant extract, and it is surprisingly not tacky. A *prima facie* case of obviousness can be overcome by "unexpected results," *i.e.*, showing that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the art would have found surprising or unexpected. *In re Soni*, 34 USPQ2d 1684, 1687 (CAFC 1995); *In re Piasecki*, 223 USPQ 785, 788 (CAFC 1984). In rejecting claims under 35 U.S.C. §103, the Examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Rijckaert*, 28 USPQ2d 1955, 1956 (CAFC 1993) (citing *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.*

The achievement of the present invention is surprising because one of ordinary skill in the art would expect an unfiltered plant extract in a mascara to be tacky. It is hard to apply a gummy mascara to the lashes. Once applied, the mascara is uncomfortable because it does not dry easily and because it can cause the upper and lower lashes to stick to one another, when it finally does dry. However, as provided in the present specification at page 8, lines 23 to 25, the mascara of the present invention surprisingly and unexpectedly performs the same as or better than conventional

mascaras. Further, as described in the present specification at page 4, lines 27 to 30, the unfiltered plant extract provides a natural fiber component to the mascara that enhances the thickness and length of the eyelashes.

As the Examiner has noted the mascara should be easy to apply, soft, uniform, and have good sensory qualities. Formulating a mascara with conventional synthetic ingredients to achieve these qualities is difficult enough. It is not expected that a mascara formula containing raw, substantially unfiltered fruits and vegetables would be able to achieve these qualities at all, nonetheless to perform comparably to conventional mascaras that are formulated to achieve these qualities with synthetically derived ingredients. Despite conventional wisdom, the mascara of the present invention containing unfiltered fruit extract (i.e., containing sticky sugar, gummy and tacky pulp and skin) is favorably compared with conventional mascaras that do not contain these ingredients and it is hard to reconcile how this could be anything but surprising. The Pastour reference, on the other hand, is no different than conventional mascaras. The ability of the mascara of the present invention to perform as well as traditional mascara is indeed unexpected because it contains nearly all of the components of the fruit or vegetable which would be expected to cause the mascara to perform poorly.

Therefore, Appellants submit the claims of the present application satisfy the requirements of 35 U.S.C. §103(a) because none of the cited references teaches or suggests a composition containing an unfiltered plant extract, and because the mascara is surprisingly and unexpectedly non-tacky. Thus, the Examiner has failed to establish a *prima facie* case of obviousness and Appellants request that the Examiner's rejection be withdrawn.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182 Group Art Unit: 1615

Filed: June 2, 1999 Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

CONCLUSION

In light of the data and the arguments presented above, the rejections of claims 1 to 8, and 10 to 30 based on anticipation and obviousness in view of the Pastour reference should be reversed as they are unfounded. The Pastour reference fails to disclose, teach or suggest a plant extract of the present invention that is an unfiltered whole processed fruit or vegetable extract of the tacky constituents of the fruit or vegetable. Accordingly, Appellants respectfully request that the Honorable Board reverse the decision of the Examiner finally rejecting the pending claims and declare that all pending claims in this application are allowable.

Respectfully submitted,

January 28, 2004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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APPENDIX: THE CLAIMS ON APPEAL

1.(currently amended) A mascara composition comprising a seedless but otherwise substantially unfiltered whole processed fruit or vegetable extract of at least tacky constituents of the fruit or vegetable selected from the group consisting of pulp and skin dispersed in a silicone oil.

2.(previously presented) The composition of claim 1 in which said whole processed fruit or vegetable extract is present in an amount of about 0.05 to about 0.50 percent by weight of the composition.

3.(previously presented) The composition of claim 2 in which said whole processed fruit or vegetable extract is present in an amount of about 0.1 to about 0.4 percent by weight of the composition.

4.(previously presented) The composition of claim 1 in which said whole processed fruit or vegetable extract is fruit-derived.

5.(original) The composition of claim 4 in which said fruit is selected from the group consisting of apple, pear, peach, mango, papaya, apricot, nectarine and combinations thereof.

6. (original) The composition of claim 5 in which said fruit is apple.

7.(previously presented) The composition of claim 1 in which said whole processed fruit or vegetable extract is vegetable-derived.

8.(original) The composition of claim 7 in which said vegetable is selected from the group consisting of yams, potatoes, peas, peppers, beans, squashes, carrots, and combinations thereof.

9.(canceled) The composition of claim 1 in which said extract is unfiltered.

10.(original) The composition of claim 1 in which said silicone oil is volatile.

11.(original) The composition of claim 10 in which said volatile oil is selected from the group consisting of cyclomethicone, hexamethylcyclotrisiloxane, octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane, and dimethylpolysiloxane.

12.(original) The composition of claim 11 in which said silicone oil is cyclomethicone.

13.(original) The composition of claim 1 in which said silicone oil is non-volatile.

14.(original) The composition of claim 13 in which said non-volatile oil is selected from the group consisting of dimethicone, cetyl dimethicone, phenyl trimethicone, lauryl trimethicone, dimethiconol, and mixtures thereof

15.(previously presented) The composition of claim 1 wherein said whole processed fruit or vegetable extract comprises natural fibers.

16.(original) The composition of claim 15 further comprising non-plant fibers selected from the group consisting of synthetic non-plant fibers and natural non-plant fibers.

17.(original) The composition of claim 16 in which said non-plant fiber is synthetic.

18.(original) The composition of claim 17 in which said synthetic fiber is selected from the group consisting of polyester, polyethylene, polypropylene, acrylic, aramid, rayon, cotton, wool, silk, nylon and blends fiber.

19.(original) The composition of claim 16 in which said non-plant fiber is natural.

20.(original) The composition of claim 19 in which said natural non-plant fiber is selected from the group consisting of chitin, etherified chitin, esterified chitin, chitosan, quaternary chitosan, and derivatives thereof.

21.(original) The composition of claim 16 further comprising an antistatic agent present in an amount of about 0.01 to about 10.00 percent by weight of the composition.

22. (original) The composition of claim 21 in which said antistatic component is selected from the group consisting of nonionic, anionic, cationic, and amphoteric surfactants; amino sugars; and mixtures thereof.

23. (original) The composition of claim 22 in which said amino sugar is chitin.

24. (original) The composition of claim 1 which also comprises a pigment.

25.(currently amended) A mascara composition comprising a seedless but otherwise substantially unfiltered whole processed fruit or vegetable extract of at least tacky constituents of the fruit or vegetable selected from the group consisting of pulp and skin dispersed in a volatile silicone oil, an antistatic component, a non-plant fiber component, and said whole processed fruit or vegetable extract comprising a natural fiber component.

26.(previously presented) The composition of claim 25 in which said whole processed fruit or vegetable extract is apple-derived.

27. (original) The composition of claim 26 in which said non-plant fiber component is nylon.

28.(original) The composition of claim 27 in which said antistatic component is chitin.

29.(original) The composition of claim 28 in which said non-plant fiber component further comprises chitin.

30.(currently amended) A mascara composition for application to the eyelashes comprising about 0.05 to about 0.50 percent by weight of the composition of a seedless but otherwise substantially unfiltered whole processed apple extract of at least tacky constituents of the fruit or vegetable selected from the group consisting of pulp and skin dispersed in a cyclomethicone, a non-plant fiber component comprising nylon and chitin, an antistatic component comprising chitin, and said whole processed apple extract comprising a natural apple fiber component.

Dockets Management Branch (HFA-305),
Food and Drug Administration,
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Rockville,
MD 20852

TIBOTEC

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Dublin, 8th December 2000

Dear Sir or Madam,

Re: Guidance for Industry, Botanical Drug Products – Comments
Docket No. 00D-1392, CDER 97113

On behalf of TIBOTEC, I wish to provide you with comments on the draft Guidance for Industry, Botanical Drug Products, of August 2000.

Introduction

TIBOTEC is an emerging, globally oriented pharmaceutical company, focused on discovering and developing superior pharmaceuticals for unmet medical needs. The scientific background of the company lies in the field of HIV infection and AIDS, infectious diseases (e.g. Leishmaniasis and tuberculosis), cancer and Alzheimer's disease.

TIBOTEC's headquarters and European R&D centre are located in Mechelen, Belgium. The US R&D laboratory, TIBOTEC, Inc., is located in Rockville, Maryland, USA. TIBOTEC's commercial activities are coordinated through TIBOTEC Pharmaceuticals Ltd., located in Dublin, Ireland. TIBOTEC Group NV was founded in 1994 by Rudi Pauwels, PhD, and Carine Claeys, pharmacist, with the objective of performing drug discovery and pre-clinical drug profiling in the focus areas. Paul Stoffels, MD, joined in 1997, when the target was extended to the establishment of an integrated pharmaceutical company. Dr. Pauwels authored the first paper describing the non-nucleoside HIV Reverse Transcriptase inhibitors (TIBO-compounds; *Nature 1990*).

TIBOTEC leverages intensive R&D efforts in AIDS drug discovery, resistance biology, and drug discovery technologies, such as ultra high-throughput screening, structure-based drug design and bio-informatics. The company has combined automation with intelligent image analysis methods to enable high-content screening of chemical libraries in cellular assays using a novel ultra high-throughput format. Drug discovery technologies, including structure-based drug design methods, are all aimed at increasing the speed and efficiency of target selection, assay design, and lead optimization.

Comments

In general, we are in agreement with the Guidance for Industry, Botanical Drug Products and we are pleased that such guidance is being drafted and will soon be available to industry.

00D-1392

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C.24

Nevertheless, we would like to express our concerns regarding the terms 'highly purified' and 'botanical drug substance' as used throughout the document. In the annex to these comments is an example of a purified botanical drug substance, upon which our concerns are based. In our opinion, this mixture should be considered as a botanical.

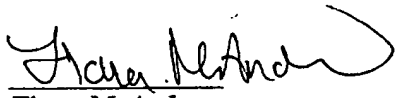
From the guidance, however, it is unclear given the level of purification as outlined in the annex, whether this botanical substance or mixture of substances is indeed considered a 'botanical'. More specifically, it is not clear if the unspecific term '.... or other similar process.' (as used in the sentence beginning 'It is prepared.....' In the definition for a Botanical Drug Substance) would apply to purification techniques such as those outlined in the example.

We therefore would like to see further clarification of the terms 'highly purified' and 'botanical drug substance' as used in this document with regard to specific stages and methods/techniques of processing.

We hope that the Centre for Drug Evaluation and Research will find these comments useful and consequently we hope to see them reflected in the final Guidance for Industry, Botanical Drug Products document.

Please contact me should you require more information or clarification.

Yours sincerely,



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ANNEX

PURIFIED BOTANICAL DRUG (SUBSTANCE)

1. INTRODUCTION

The composition of a botanical drug may vary from very complex and poorly defined (an extract) to a (partially) defined purified extract using different purification techniques.
The product referred to in the comment document is a purified botanical drug obtained by the process described in more detail below.

2. PROCESS

Basically the production process consists of 3 steps:

- solid-liquid extraction of plant leaves
- liquid-liquid extraction and washing (purification)
- additional purification

The result of this process is a (partially) defined botanical extract.

2.1. Extraction

Dried and milled plant leaves are extracted with ethanol 70° by repeated maceration overnight and percolation, at a ratio plant material:alcohol of 1:5.

2.2. Initial purification

The ethanolic botanical extract is concentrated and purified by consecutive liquid-liquid extractions. These extractions facilitate the removal of lipid constituents (water//hexane) and water-soluble components (water/butanol). The semi-purified botanical extract is obtained by precipitation in aceton and washing with other organic solvents.

2.3. Purification

The final purification is performed using one or more different purification techniques.
Tannins are removed on a gel (Sephadex).
Filtration on a reversed phase packing possibly removes more polar and/or more lipophylic fractions.

Depending on the technique(s) used, a purified extract with a different composition can be obtained. The purified extract contains at least 6 identified active compounds and a matrix consisting of related compounds (unidentified but structurally related compounds) and other unknown compounds (such as inorganic salts).

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DESTINATION G A I

1 From (Sender)

Account no.

Sender's name: Fiona McAndrew

Sender's reference *first twelve characters will be shown on invoice*

UCB PHARMACEUTICALS

UCB SA

BLANCHARDSTOWN CORPORATE PARK

BLANCHARDSTOWN DUBLIN 15

Postcode

Phone / Fax / Telex: 353 1 8208114

2 To (Receiver)

Food + Drug Administration

Dockets Management Branch (HFA-305)

5630 Fishers Lane, rm 1061

Rockville, MD 20852

Postcode: 20852 USA

Contact person: Yuan-Yuan Chiu

Phone / Fax / Telex: 301 827 4573

5 Sender's authorisation and signature

We agree that DHL's standard terms apply to this shipment and limit DHL's liability. The Warsaw Convention may also apply (see reverse). We understand that DHL does not transport cash or dangerous goods (see reverse).

Signature: Fiona McAndrew

Date: 8/12/00

3 Shipment details

Not all payment and service options are available in all countries.

Services

- [X] DOCUMENT
- [ ] WORLDWIDE PARCEL EXPRESS *all declarables*
- [ ] INTRA EC *(in free circulation)*
- [ ] EXPRESS DOCUMENT
- [ ] DOMESTIC
- [ ] WORLDMAIL *Airmail/Printed Matter specify one*
- [ ] OTHER SERVICE ..... *specify*

Transport charges *If left blank sender pays transport charges*

- [X] Sender
- [ ] Cash / Cheque / Credit Card *For approved customers only*
- [ ] External Billing Agreement
- [ ] Transport Collect

Shipment insurance *see reverse*

- [ ] YES

Full description of contents

Documents

International Worldwide Parcel Express shipments only

Declared Value for Customs *give currency*

Sender's VAT / GST no.

Harmonised commodity code *if applies*

Receiver's VAT / GST no. or EIN / SSN

Type of export: [ ] PERMANENT [ ] REPAIR/RETURN [ ] TEMPORARY

Destination duties / taxes *If left blank receiver pays duties / taxes*

[ ] Receiver [ ] Sender [ ] Other ..... *Specify destination approved account number*

4 Size and weight

No. of pieces: 1

Weight: .5 kg

Dimensions *cm L x W x H*

VOLUMETRIC/CHARGED WEIGHT kg

CODES	CHARGES
	Services
	Special
	Insurance
	Other /VAT
CURRENCY CODE	TOTAL

TRANSPORT COLLECT STICKER No.

PICKED UP BY

Route No. DA12

Time 1205

Date 11-12-00

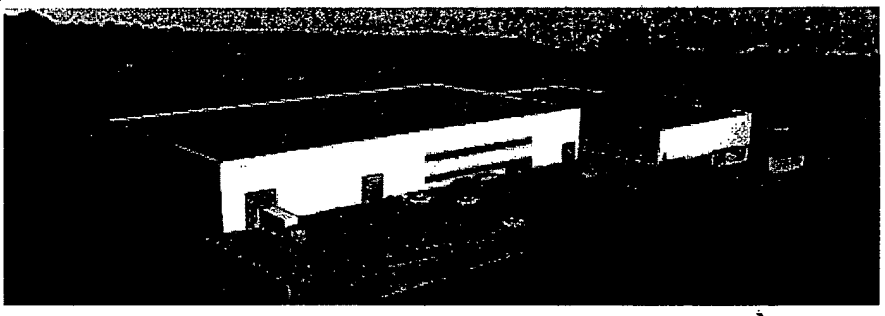
l'Ami des ingrédients naturels

April 2001 • Nr 27

Towards an ethics for development «natural»?

bringing substance capable of supporting the values of natural brands to the green label

We are pleased to announce the extension project of our manufacturing unit in Fontenay Sur Eure : Adonis. This new factory is dedicated to all of you, readers of l'AMI - who have made the choice of quality by Le Natural Product Designer*. This project is also a result of the still strong and growing vogue for natural products.



At the beginning of this new millennium, the panicking fear of the mad cow or genetically modified organisms even seem to add a further dimension to the «green wave». Is there only some agreement on the definition of the word natural?

Is the chamomile extract in this shampoo the same chamomile shown on the packaging of this soothing cream? They have the same INCI name.... The wave may well be just... a wave precisely: rising and rolling on... nothing.

Would this all be but wind ? No. At least this is the answer we have been trying to substantiate since the first issues of l'AMI - it may even be the vocation of this news letter.

Continued P3

These molecules we extract

These molecules we extract and we call «cosmetic actives» are mostly generated by the secondary metabolism of plants (the primary one involving respiration and photosynthesis). In particular, they allow the adaptation of plants to their environment.

Adaptation to the environment

To cold

Plants of temperate climates adapt themselves to cold. Frost provokes ice crystals in cells, which damage their membranes and kill them. The most visible defence system to avoid this phenomenon is the loss of leaves in winter. Moreover, an accumulation of «antigel» molecules takes place in some plants (amino-acids, carbohydrates and derivatives) to lower the freezing point of the plant.

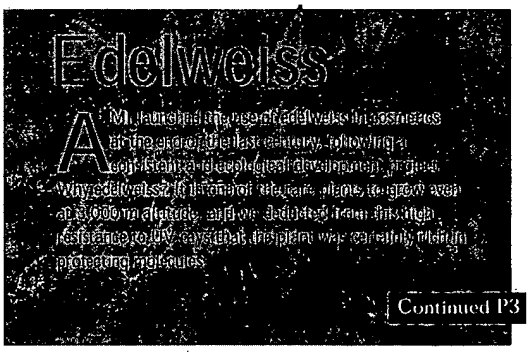
To aggression of parasites, predators, disease

Again, plants synthesize defensive and protective active molecules, mostly antibacterial and anti-fungal (particularly in essential oils) and even toxic to avoid consumption by animals.

To altitude

Further to the cold and dry conditions it generates, the mountain environment submits plants to another aggression: that of UV rays, the quantity of which increases by about 7 % each 300 m in altitude. This explains why plants rise in tiers on mountains. They become rarer and smaller with altitude. Besides these modifications visible to the bare eye, plants which resist to high altitude develop a protecting system of molecules able to screen out UV rays.

Continued P2



These molecules we extract (suite)

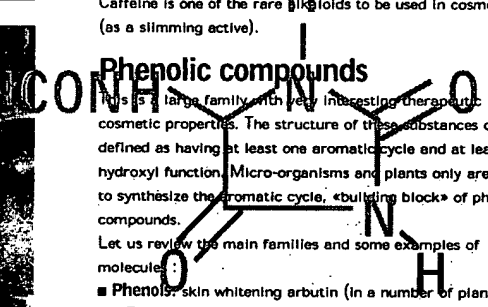
The large molecule families of the secondary metabolism

Terpenoids

They include phytohormones, numerous aromatic compounds particularly present in essential oils, the important carotenoid group, etc.

Alkaloids

They are often toxic molecules: curare, strychnine, cocaine. Caffeine is one of the rare alkaloids to be used in cosmetics (as a slimming active).



Phenolic compounds

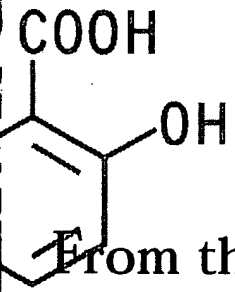
This is a large family with very interesting therapeutic and cosmetic properties. The structure of these substances can be defined as having at least one aromatic cycle and at least one hydroxyl function. Micro-organisms and plants only are able to synthesize the aromatic cycle, «building block» of phenolic compounds.

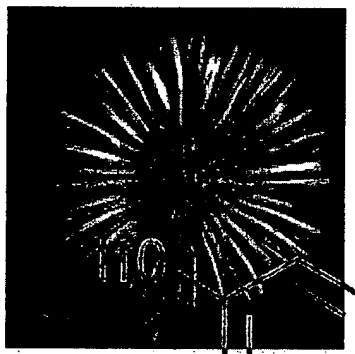
Let us review the main families and some examples of molecules :

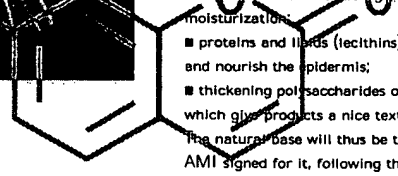
- **Phenols:** skin whitening arbutin (in a number of plants of the Ericaceae family, particularly bearberry).
- **Phenolic acids:** salicylic acid and its derivatives (in willow bark and meadowsweet) which have anti-inflammatory properties: they are at the origin of aspirin.
- **Tannins:** which combine to proteic molecules. Due to this property, they allow to «waterproof» the upper layers of the epidermis and protect the layers underneath.
- **Coumarins**[1]: there are about a thousand of them. Let us quote umbelliferone, present in particular in mouse-ear, and its bacteriostatic properties.
- **Flavonoids:** more than 3 000, they have a common biosynthetic origin. They are pigments widely spread in plants. Flavonoids are mainly known for their protecting activity on small blood vessels and their free radical scavenging properties (notably against the peroxidation of cell membrane lipids).

Some of them belong to the «collective unconscious» of the cosmetic industry: hyperoside of St John's wort, PCO of grape seeds, anthocyanins of red vine, soybean isoflavones, sylimarin of blessed thistle or gingketin of ginkgo.

1. Coumarins come from the vernacular name of the tonka bean: coumarou, from which coumarin was isolated in 1820.







From the molecule to the formula : the new Frontier of natural

Many molecules reviewed hereabove are used as cosmetic active principles under the form of extracts at doses hardly ever exceeding 0.5 %.

It then is quite easy to understand that this concentration shall not be enough for a product to be qualified of natural. The proportion of «natural» can be substantially increased if working the base of the formula with plant derived formulation ingredients moreover displaying biological properties:

- vegetable oils which can go in the oily phase or emulsions while improving moisturization;
- proteins and lipids (lecithins), some of them being emulsifying, which protect and nourish the epidermis;
- thickening polysaccharides or gelling agents (carragheenans, gums...) which give products a nice texture while moisturizing the skin.

The natural base will thus be the next cosmetic territory to investigate. AMI signed for it, following the same philosophy as for plant extracts: rigour and objectivity.

Our laboratories are at your disposal to go even further. So give your skin a new start for the third millenary with cosmetics made of all natural and active ingredients!

increase the proportion of natural in cosmetic products by working the formula up

«natural» ?

Natural ? Maybe should we start with a definition of the word or at least to review the semantic territory it covers.
An ingredient is said «natural» when derived from vegetable resources, with high care not to damage its nature.
It is the case for herbal extracts, provided the extraction process respects the nature of the extracted molecules.
Historical source of skin care materials, natural products, traditionally ill-defined, have been slowly overtaken by scientific synthetic chemicals.
But this is not enough to dismiss their potential: powerful analytical techniques as well as modern agriculture provide the conditions for a rational renewal of natural skin care based on the numerous biologically active molecules synthesized by the plants. Viewed from the angle of vegetable chemistry, natural products may indeed satisfy the expectations of scientists as well as those of consumers: the vegetable molecule bridges the gap between the world of plant and the formulation laboratory, between the marketing story and efficacy.

the vegetable molecule bridges the gap between the world of plant and the formulation laboratory, between the marketing story and efficacy

If the industry has long questioned its members on the subject of myth and reality, the vegetable molecule, the missing link of cosmetics, is finally bringing the best of both world together.

The molecule perspective allows a complete organization of the natural supply chain:

- in order to optimize the yield in active materials of the plant, terms and conditions are precisely defined with producers;
- extraction techniques are designed to obtain the molecule in a stable and usable form;
- analytical methods are defined to guarantee the presence and the concentration of the molecule in the product;
- extracts are standardized for reproducible evaluation tests.

a lot of brands have engaged on a road of quality

All these guarantees condition the value and legitimacy of natural products. And it is on this validated ground that the natural label may authorize brands to write claims actually in relation to facts. Because they... deserve it !
It is true that when naturals become so important, many laboratories have decided to buy the label at the lowest cost: an INCI name is bought at the cheapest price. But the continuous growth of the Alban Muller Group also testifies that a lot of brands have engaged on the road to quality - looking for precisely defined products with reliable guarantees on the origin and the manufacturing process.

to seize the full meaning of naturals

The Alban Muller Group now offers product development assistance service in 45 countries.
Experts help you determine the technical parameters of you project - their laboratories and manufacturing units become yours to develop products adapted to your needs - but also adapted to the ethics of your brands : to seize the full meaning of naturals.



Meetings

Vitafoods
APRIL 24-26 • GENEVA • AMI VARISTOR
Catherine Douay catherine_douay@compuserve.com
Fabienne Kirchenbaum fabienne.kirchenbaum@albanmuller.com
Isabelle Nault isabelle.nault@albanmuller.com
Jean-Marc Seigneuret jmseig@albanmuller.com
Varistor info@vari-food.ch
Expect your visit at Palexpo - Booth 1512
1218 Le Grand-Saconnex - Geneva - Switzerland

In-cosmetics
APRIL 24-26 • DÜSSELDORF • AMI WORLEE
Adeline Courtier adeline.courtier@albanmuller.com
Ariane Csendes ariane.csendes@albanmuller.com
Armelle Magré amagre@albanmuller.com
Alban Muller the_boss@albanmuller.com
Worlee Mschwoy@ch.worlee.de
Expect your visit at Messe-Center - Booth 260
Hall 3 - Düsseldorf - Germany

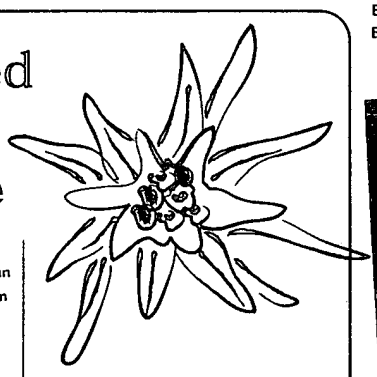
X Congreso Nacional de la Química Cosmética
MAY 17-20 • IXTAPA ZIHUATANEJO • AMI ABA
«Nature and science at the service of the cosmetic industry»
Alban Muller the_boss@albanmuller.com
Reinhard Richter aba_veritas2@infosel.net.mx
Expect your visit on Alban Muller's lecture
at Meliá Azul Ixtapa Resort & Conference Center
Ixtapa Zihuatanejo - Mexico

SFC
JUNE 6-7 • PARIS
Alban Muller International expects your visit on the occasion of the 50th anniversary of the SFC at Palais des Congrès de Paris - Level 2 - Hall Maillot A
Contact Sophie Lemoine sophie.lemoine@albanmuller.com

HBA
JULY 24-26 • SAO PAULO • AMI PIC
Alban Muller the_boss@albanmuller.com
The team PIC QUIMICA import@pic-quimica.com.br
Expect your visit at Expo Center Norte
Booth 150 - Sao Paulo - Brazil

Reasonable and integrated use of nature

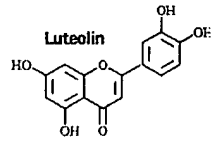
Edelweiss : a successful example

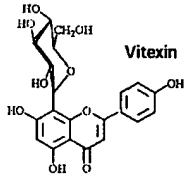


Adaptation to altitude by an increased synthesis of polyphenols

True mascot of the Alpine region and symbol of purity, edelweiss is a small annual plant with a fleecy aspect. What seems to be flowers are in fact the leaves disposed in a star shape and with a more fleecy aspect than the rest of the plant. The actual flowers are very small and not very decorative.
Edelweiss geographical origin is the Siberian steppes, where it resists to deep cold thanks to its downy and insulating coating made of thin hollow hairs.
Edelweiss grows mostly in rocky and sunny high mountain pastures, or calcareous rocks at an altitude of 800 to 3 000 m. It blossoms from June to September. It can grow in the snow, which gives it its image of purity and whiteness.
To be able to cope with such harsh climatic conditions, the plant must have adapted itself by a natural protective system not only against the cold, but also against U.V. rays which are particularly abundant at high altitudes. This physiological defence system consists in an efficient array of molecules resulting from the secondary metabolism with screening and antioxidant properties. The following molecules were put in evidence :

- flavonoids, particularly luteolin and apigenin and their glucosides : luteolin-7-glucoside and apigenin-7-glucoside, vitexin-2-rhamnoside ;
- phenolic acid of the cafeyl quinic type.





From an ecological point of view

Collecting edelweiss is submitted to regulations. We therefore set up a contract of integrated farming culture, within a programme of restoration of the Alpine sites.

Edelweiss: a cosmetic dream

From the German words edel, noble, and weiss, white, «edelweiss» itself evokes snowy summits, purity, original nature.
In other words, it is an invitation to breathe the purest atmosphere thanks to extracts rich in protective molecules.
AMI offers in standard a watersoluble extract (propylene glycol) and an extract titrated in flavonoids (water and propylene glycol).

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Société Anonyme au capital de 40 000 €
RCS de Créteil numéro B 415 392 422
Président : Alban MULLER - Directeur Général : Laurent MULLER

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Regeneration : *millenium green*

According to the prophets, God created three realms that fill the three heavens. The first sphere, the love sphere, is red, the second sphere or sphere of wisdom is blue, the third sphere, sphere of creation, is green. Expressing soul regeneration, green also conveys the fecund union between water and earth. It stands for natural rebirth at ngtime, for renewal. It is the colour of youth, the colour of promises of a good arvest. Highly refreshing, green means sap, vegetable blood, life bud. Green also stands for harmony and serenity. It soothes emotions, eases a tense atmosphere, stimulates respiration and is an invitation to inner peace. It is a damp and lively colour, the colour of calm. Now then, why not come ind concoct new products? Come and have a rest for a cosmetic picking of ens. To feel fresh as running water, frisky as young herbs, sparkling as young shoots. To get a good dose of energy and colour your cosmetics with sharp hints. AMI presents its Spring regenerating selection of titrated extracts : watercress, fennel and cucumber with tonic, free-radical scavenging and moisturizing virtues.

If Inner beauty is a question of balance, I expect products to maintain and supplement the delicate mechanism of my skin

Free-radical scavenging fennel

Fennel has soothing, antiseptic, scrubbing, purifying and free radical scavenging properties. Fennel extracts can be used in body care products (scrubbing creams and gels), soothing care for the eye contour, face products for tired, sensitive and mature skin and also in hand products. The seed contains glucids (oses and osides), protids (16 to 20 % proteins), 17 to 20 % lipids, mineral matters (calcium, potassium), organic acids (citric, fumaric, malic, tartaric, ascorbic), phenolic compounds (phenolic acids -caffeic, ferulic, paracoumaric), flavonoids of the flavonol type (quercetine and kaempferol derivatives), coumarins, terpenoids (triterpenes and carotenoids), vitamins (B1, B2, B3, B5, B6), 2 to 6 % essential oil: AMI offers an extract titrated in pheneolic compounds.

Foeniculum vulgare Mill.

Moisturizing cucumber

Cucumber has moisturizing and refreshing properties. It can be used in many cosmetic extracts, especially in face creams (dry and sensitive skin) and in after-sun products. The fresh pulp and the juice have soothing properties, they relieve skin and scalp irritations. Cucumber fruit contain osides (sucrose), protids among which amino acids (arginine) and enzymes (carboxylase, diastase), lipids, mineral matters (copper, iron, iodine, magnesium and zinc), organic acids (ascorbic acid), terpenoids (carotenoids), vitamins (thiamine, adenine). An extract titrated in proteins is available.

Cucumis sativus L.

Tonic watercress

Nasturtium officinale R. Br

Watercress has astringent, purifying, remineralizing and tonic activities. Watercress extracts are particularly appreciated in hair care products (for greasy hair, delicate and damaged hair) and against hair loss. They are also appreciated in body and mouth products. Lastly, watercress is a first choice ingredient in face care products for combination, oily and mature skin. Watercress contains sulphurated derivatives, mineral matters (calcium, iron, iodine, manganese and potassium), organic acids among which ascorbic acid, vitamins (retinol, carotenoids, thiamine, riboflavine and calciferol). The extract offered by AMI is titrated in flavonoids.

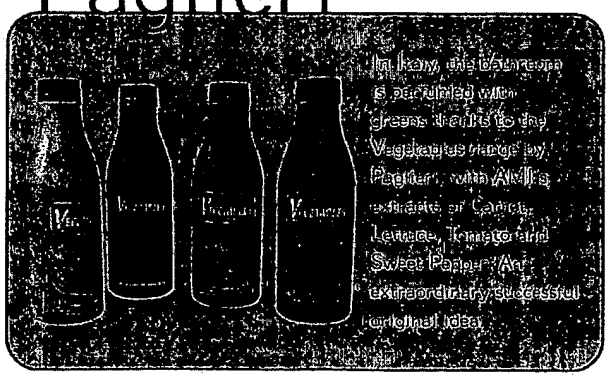
Jardins de Beauté

nce upon a time was Jardins ... de Beauté or the Nidoberry of Potimarron®, ... highlights all the resources and the creativity of ... the Natural Product Designer®, from the new plant extract ... laboratory development to the marketing and commercial back-up via ... formulation consultancy.

Native to South America, it is at the Ferme de Sainte Marthe in Sologne - centre of reference since then European Centre for Organical Farming that this funny fruit-vegetable was introduced in France 20 years ago. Looking like a pumpkin but tasting like horsechestnut, its cultivar was called Potimarron®.

Appreciated for its gustative and nutritional qualities, Potimarron® disclosed other virtues : ... made the skin of its harvesters smoother and smoother. Given these puzzling qualities, a real ... team was set up and Jardins de Beauté (Gabriel Dorey supported by AMI's infrastructure and ... experience) was born. Analysis revealed that Potimarron was crammed with provitamin A. ... Tests and checks succeeded one another in our laboratories during several years until an ... extract was obtained, prelude to a whole range of finished cosmetics. The marketing and ... commercial operations then took over: claims of the range, leaflets, packaging ... launched in the «active spaces» of the Carrefour hypermarkets, Jardins de Beauté ... marketed more discreetly a whole range of products based on this new incomparable ... biological base. First in Europe, this range boasted with the special mention «biological ... organic range». AMI further offered a true high-rank bosky bower to this precious ... active principle, thanks to its first press vegetable oils and natural emulsifiers. ... After the stunning feeling of freshness and the euphoria of renewal, have a ... tango with the elegant generosity of greediness, be sure of your skin ... with healthy products.

Paglieri



In Italy, the bathroom is perfumed with greens, thanks to the Vegetables range by Paglieri, with AMI's extracts of Carrot, Lettuce, Tomato and Sweet Pepper. An extraordinary successful original idea.

CONTACT : info@albanmuller.com

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR173.240]

[Page 126-127]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 173--SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION--

Subpart C--Solvents, Lubricants, Release Agents and Related Substances

Sec. 173.240 Isopropyl alcohol.

Isopropyl alcohol may be present in the following foods under the conditions specified:

(a) In spice oleoresins as a residue from the extraction of spice, at a level not to exceed 50 parts per million.

(b) In lemon oil as a residue in production of the oil, at a level not to exceed 6 parts per million.

[[Page 127]]

(c) In hops **extract** as a residue from the extraction of hops at a level not to exceed 2.0 percent by weight: Provided, That,

(1) The hops **extract** is added to the wort before or during cooking in the manufacture of beer.

(2) The label of the hops **extract** specifies the presence of the isopropyl alcohol and provides for the use of the hops **extract** only as prescribed by paragraph (c)(1) of this section.

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[**CITE: 21CFR184.1262**]

[Page 491-492]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.**1262** Corn silk and corn silk extract.

(a) Corn silk is the fresh styles and stigmas of Zea mays L. collected when the corn is in milk. The filaments are extracted with dilute ethanol to produce corn silk extract. The extract may be concentrated at a temperature not exceeding 60 deg.C.

(b) The Food and Drug Administration, in cooperation with the National Academy of Sciences, is developing food-grade specifications for corn silk and corn silk extract. In the interim, this ingredient must be of a suitable purity for its intended use.

(c) In accordance with Sec. 184.1(b)(2), the ingredients are used in food only within the following specific limitations:

[[Page 492]]

Category of food	Maximum level of use in food (as served)\1\	Functional use
Baked goods and baking mixes, Sec. 170.3(n)(1) of this chapter.	30	Flavoring agent, Sec. 170.3(o)(12) of this chapter.
Nonalcoholic beverages, Sec. 170.3(n)(3) of this chapter.	20	Do.
Frozen dairy desserts, Sec. 170.3(n)(20) of this chapter.	10	Do.
Soft candy, Sec. 170.3(n)(38) of this chapter.	20	Do.
All other food categories.....	4	Do.

\1\ Parts per million.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[47 FR 29953, July 9, 1982]

[Code of Federal Regulations]
[Title 21, Volume 6]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR573.520]

[Page 497]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS--Table of

Subpart B--Food Additive Listing

Sec. 573.520 Hemicellulose **extract**.

Hemicellulose **extract** may be safely used in animal feed when incorporated therein in accordance with the following conditions:

(a) The additive is produced from the aqueous **extract** obtained by the treatment of wood with water at elevated temperatures (325 degrees-535 degrees F) and pressure (80 to 900 pounds per square inch) and contains primarily pentose and hexose sugars.

(b) The additive may be used in a liquid or dry state with the liquid product containing not less than 55 percent carbohydrate and the dry product containing not less than 84 percent carbohydrate.

(c) The additive is used as a source of metabolizable energy in animal feed in accordance with good manufacturing and feeding practices.

[41 FR 38652, Sept. 10, 1976, as amended at 43 FR 11181, Mar. 17, 1978]

[Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2001]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1445]

[Page 516]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1445 Malt syrup (malt **extract**).

(a) Malt is the product of barley (Hordeum vulgare L.) germinated under controlled conditions. Malt syrup and malt **extract** are interchangeable terms for a viscous concentrate of water **extract** of germinated barley grain, with or without added safe preservative. Malt syrup is usually a brown, sweet, and viscous liquid containing varying amounts of amylolytic enzymes and plant constituents. Barley is first softened after cleaning by steeping operations and then allowed to germinate under controlled conditions. The germinated grain then undergoes processing, such as drying, grinding, extracting, filtering, and evaporating, to produce malt syrup (malt **extract**) with 75 to 80 percent solids or dried malt syrup with higher solids content.

(b) FDA is developing food-grade specifications for malt syrup (malt **extract**) in cooperation with the National Academy of Sciences. In the interim, the ingredient must be of a purity suitable for its intended use.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as defined in Sec. 170.3(o)(12) of this chapter.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 51613, Nov. 10, 1983]

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.**1560** Ox bile extract.

(a) Ox bile extract (CAS Reg. No. 8008-63-7), also known as purified oxgall or sodium choleate, is a yellowish green, soft solid, with a partly sweet, partly bitter, disagreeable taste. It is the purified portion of the bile of an ox obtained by evaporating the alcohol extract of concentrated bile.

(b) Food-grade ox bile extract shall meet the specifications of the U.S. Pharmacopeia (USP), XIV, 1950, p. 410.\1\

\1\ Copies may be obtained from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

(c) The ingredient is used as a surfactant as defined in Sec. 170.3(o)(29) of this chapter.

(d) The ingredient is used in food in accordance with Sec. 184.1(b)(1) at levels not to exceed good manufacturing practice. Current good manufacturing practice results in a maximum level, as served, of 0.002 percent for cheese as defined in Sec. 170.3(n)(5) of this chapter.

(e) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[43 FR 36064, Aug. 15, 1978. Redesignated and amended at 50 FR 49537, Dec. 3, 1985]

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 172--FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTIO

Subpart F--Flavoring Agents and Related Substances

Sec. 172.580 Safrole-free **extract** of sassafras.

The food additive safrole-free **extract** of sassafras may be safely used in accordance with the following prescribed conditions:

(a) The additive is the aqueous **extract** obtained from the root bark of the plant Sassafras albidum (Nuttall) Nees (Fam. Lauraceae).

(b) It is obtained by extracting the bark with dilute alcohol, first concentrating the alcoholic solution by vacuum distillation, then diluting the concentrate with water and discarding the oily fraction.

(c) The purified aqueous **extract** is safrole-free.

(d) It is used as a flavoring in food.

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION--Table of Contents

Subpart A--Foods

Sec. 73.170 Grape skin **extract** (enocianina).

(a) Identity. (1) The color additive grape skin **extract** (enocianina) is a purplish-red liquid prepared by the aqueous extraction (steeping) of the fresh deseeded marc remaining after grapes have been pressed to produce grape juice or wine. It contains the common components of grape juice; namely, anthocyanins, tartaric acid, tannins, sugars, minerals, etc., but not in the same proportions as found in grape juice. During the steeping process, sulphur dioxide is added and most of the extracted sugars are fermented to alcohol. The **extract** is concentrated by vacuum evaporation, during which practically all of the alcohol is removed. A small amount of sulphur dioxide may be present.

(2) Color additive mixtures for food use made with grape skin **extract** (enocianina) may contain only those diluents listed in this subpart as safe and suitable in color additive mixtures for coloring foods.

(b) Specifications. Grape skin **extract** (enocianina) shall conform to the following specifications:

Pesticide residues, not more than permitted in or on grapes by regulations promulgated under section 408 of the Federal Food, Drug, and Cosmetic Act.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.

(c) Uses and restrictions. Grape skin **extract** (enocianina) may be safely used for the coloring of still and carbonated drinks and ades, beverage bases, and alcoholic beverages subject to the following restrictions:

(1) It may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless artificial color is authorized by such standards.

(2) Its use in alcoholic beverages shall be in accordance with the provisions of parts 4 and 5, title 27 CFR.

(d) Labeling requirements. The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of Sec. 70.25 of this chapter. The common or usual name of the color additive is ``grape skin **extract**'' followed, if desired, by ``(enocianina)''.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION--Table of Contents

Subpart A--Foods

Sec. 73.30 Annatto **extract**.

(a) Identity. (1) The color additive annatto **extract** is an **extract** prepared from annatto seed, Bixa orellana L., using any one or an appropriate combination of the food-grade extractants listed in paragraph (a)(1) (i) and (ii) of this section:

(i) Alkaline aqueous solution, alkaline propylene glycol, ethyl alcohol or alkaline solutions thereof, edible vegetable oils or fats, mono- and diglycerides from the glycerolysis of edible vegetable oils or fats. The alkaline alcohol or aqueous extracts may be treated with food-grade acids to precipitate annatto pigments, which are separated from the liquid and dried, with or without intermediate recrystallization, using the solvents listed under paragraph (a)(1)(ii) of this section. Food-grade alkalis or carbonates may be added to adjust alkalinity.

(ii) Acetone, ethylene dichloride, hexane, isopropyl alcohol, methyl alcohol, methylene chloride, trichloroethylene.

(2) Color additive mixtures for food use made with annatto **extract** may contain only diluents that are suitable and that are listed in this subpart as safe in color additive mixtures for coloring foods.

(b) Specifications. Annatto **extract**, including pigments precipitated therefrom, shall conform to the following specifications:

(1) Arsenic (as As), not more than 3 parts per million; lead as Pb, not more than 10 parts per million.

(2) When solvents listed under paragraph (a)(1)(ii) of this section are used, annatto **extract** shall contain no more solvent residue than is permitted of the corresponding solvents in spice oleoresins under applicable food additive regulations in parts 170 through 189 of this chapter.

(c) Uses and restrictions. Annatto **extract** may be safely used for coloring foods generally, in amounts consistent with good manufacturing practice, except that it may not be used to color foods for which standards of identity have been promulgated under section 401 of the act unless added color is authorized by such standards.

(d) Labeling. The label of the color additive and any mixtures prepared therefrom and intended solely or in part for coloring purposes shall conform to the requirements of Sec. 70.25 of this chapter. Labels shall bear information showing that the color is derived from annatto seed. The requirements of Sec. 70.25(a) of this chapter that all ingredients shall be listed by name shall not be construed as requiring the declaration of residues of solvents listed in paragraph (a)(1)(ii) of this section.

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(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health and

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 73--LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION--Table of Contents

Subpart A--Foods

Sec. 73.100 Cochineal **extract**; carmine.

(a) Identity. (1) The color additive cochineal **extract** is the concentrated solution obtained after removing the alcohol from an aqueous-alcoholic **extract** of cochineal (Dactylopius coccus costa (Coccus cacti L.)). The coloring principle is chiefly carminic acid.

(2) The color additive carmine is the aluminum or calcium-aluminum lake on an aluminum hydroxide substrate of the coloring principles, chiefly carminic acid, obtained by an aqueous extraction of cochineal (Dactylopius coccus costa (Coccus cacti L.)).

(3) Color additive mixtures for food use made with cochineal **extract** or carmine may contain only diluents that are suitable and that are listed in this

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subpart as safe in color additive mixtures for coloring foods.

(b) Specifications. (1) Cochineal **extract** shall conform to the following specifications:

pH, not less than 5.0 and not more than 5.5 at 25 deg.C.
Protein (N x 6.25), not more than 2.2 percent.
Total solids, not less than 5.7 and not more than 6.3 percent.
Methyl alcohol, not more than 150 parts per million.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 1.8 percent.

(2) Carmine shall conform to the following specifications:

Volatile matter (at 135 deg.C. for 3 hours), not more than 20.0 percent.
Ash, not more than 12.0 percent.
Lead (as Pb), not more than 10 parts per million.
Arsenic (as As), not more than 1 part per million.
Carminic acid, not less than 50.0 percent.

Carmine and cochineal **extract** shall be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms. Pasteurization or such other treatment is deemed to permit the adding of safe and suitable substances (other than chemical preservatives) that are essential to the method of pasteurization or other treatment used. For the purposes of this paragraph, safe and suitable substances are those substances that perform a useful function in the pasteurization or other treatment to render the carmine and cochineal **extract** free of viable Salmonella

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CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--CONTINUED

PART 169--FOOD DRESSINGS AND FLAVORINGS--Table of Contents

Subpart B--Requirements for Specific Standardized Food Dressings and Flavorings

Sec. 169.**175** Vanilla extract.

(a) Vanilla extract is the solution in aqueous ethyl alcohol of the sapid and odorous principles extractable from vanilla beans. In vanilla extract the content of ethyl alcohol is not less than 35 percent by volume and the content of vanilla constituent, as defined in Sec. 169.3(c), is not less than one unit per gallon. The vanilla constituent may be extracted directly from vanilla beans or it may be added in the form of concentrated vanilla extract or concentrated vanilla flavoring or vanilla flavoring concentrated to the semisolid form called vanilla oleo-resin. Vanilla extract may contain one or more of the following optional ingredients:

(1) Glycerin.
(2) Propylene glycol.
(3) Sugar (including invert sugar).
(4) Dextrose.
(5) Corn sirup (including dried corn sirup).

(b)(1) The specified name of the food is ``Vanilla extract'' or ``Extract of vanilla''.

(2) When the vanilla extract is made in whole or in part by dilution of vanilla oleoresin, concentrated vanilla extract, or concentrated vanilla flavoring, the label shall bear the statement ``Made from _____'' or ``Made in part from _____'', the blank being filled in with the name or names ``vanilla oleoresin'', ``concentrated vanilla extract'', or ``concentrated vanilla flavoring'', as appropriate. If the article contains two or more units of vanilla constituent, the name of the food shall include the designation ``__-fold'', the blank being filled in with the whole

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number (disregarding fractions) expressing the number of units of vanilla constituent per gallon of the article.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the labeling required by paragraph (b)(2) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(c) Label declaration. Each of the ingredients used in the food shall be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

[42 FR 14479, Mar. 15, 1977, as amended at 58 FR 2886, Jan. 6, 1993]

ExtractsPlus Recommends Guidelines for FDA Regulations in the Nutritional Supplement Industry

JAN. 21. 12:55AM

PRESS RELEASE

For Release, Immediately
Date: January 15,1998

For more information, call Staci Eisner, Technical Director
or Bill Roberts, President

Carlsbad, CA.-- The FDA's recent labeling rule has sparked heated discussion in the health supplement industry. This reaction led the FDA to invite industry input. ExtractsPlus, a distributor of botanical extracts, responded with specific recommendations. The main provisions of ExtractsPlus' petition can be summarized as follows:

1. Establish definitions for botanical extracts.

In order to implement rules for the labeling of botanical extracts, it is essential first to define what constitutes such an extract. There are a great variety of materials represented, with a greater or lesser degree of accuracy, as plant extracts. For example, there may be confusion between the pressed, dried juice of a plant and the extracts of the plant. Furthermore, the term "native extract" is often misunderstood. ExtractsPlus has proposed specific definitions for terms related to botanical extracts.

2. Establish a methodology to distinguish different types of extracts, without requiring confusing statements about the solvents used.

The FDA's latest ruling requires product labels to disclose the solvents used to make an extract, even when the solvents are removed to dryness. Extracts made from the same herb but using different solvents can have very different biochemical properties. For example, the beneficial fatty acids found in saw palmetto can only be extracted using special solvents which are chemically compatible with the fatty acids. For this reason, it is important for consumers to know how the extracts they buy were made Then if they are dissatisfied with the results obtained with one type of extract, they could switch to a different type.

Some members of the nutritional supplement industry are concerned that the practice of listing solvents may lead consumers to erroneously believe that significant solvent residues remain in the products. To avoid this confusion ExtractsPlus is proposing a system of solvent categorization. For example water-based extracts would be in one category, ethanol-based extracts in another, and so on. Product labels would list the category of solvent. The explicit naming of the solvent would be

unnecessary.

ExtractsPlus believes this scheme would help educate consumers to differentiate between products nominally containing the same herb. It would also assist marketers in creating brand distinction, and dosage form manufacturers in buying consistent raw materials.

3. The terms "extracts" and "raw herbs" should not be used interchangeably

Some manufacturers of health supplements use extracts as the "source" of an herb. For example, they might use 1 mg of a 50:1 extract and then label the product as containing 50 mg of herb. This sourcing is misleading to the consumer, and shows the great variance in potency of herbal supplements that may currently have the same information on their labels. An extract by definition cannot contain all the components of the raw herb. Therefore an extract should never be considered or used as the source of a plant for manufacturing purposes.

4. Plant:extract ratio notation should be clarified and disclosed.

The FDA's latest ruling defines a plant:extract ratio for use on the rebels of liquid extracts, but ignores any similar provision for powdered extracts. ExtractsPlus believes that this is a serious omission. Currently, there are several alternative ways to notate the plant:extract ratio. Let's say 4 kilos of herb are processed into 1 kilo of extract. The resulting powder could be described as a 4:1, a 1:4 or a 4x extract. When fillers are included in the computation of ratios, the issue is further complicated. The ratio confusion is exacerbated as it extends from the raw materials to the end product purchased by the buying public. ExtractsPlus recommends that the FDA establish standards for ratio notation used in labeling powdered extracts.

5. Amount of filler in powdered extracts should be taken into account

Even when plant:extract ratios are the same, the amount of filler used in powdered extracts can vary considerably. For example, a crude plant extract containing no filler would typically have a ratio of 5:1 and would contain a broad spectrum of the components naturally occurring in the plant. However, a 5:1 extract could also be manufactured by diluting a highly concentrated 100:1 extract with 95% filler. This latter extract would contain only a few of the plant's native principles. ExtractsPlus believes that it is important for consumers, formulators, and supplement manufacturers alike to discern the amount of filler. This can be handled either by excluding the amount of filler in the calculation of extract ratios, or explicitly stating the filler volume on product labels.

6. Supplement manufacturers, above all, need access to vital information.

Due to the complexity of the botanical extract market, it is difficult to formulate labeling guidelines which will accurately and universally convey each product's important qualities to the consumer. However, in order to ensure consistent quality, ExtractsPlus recommends that supplement manufacturers, at least, have access to all of this information, including:

- extraction solvent (type and concentration)

- plant:extract ratio, including ranges if applicable

- complete ingredient disclosure (including the type and concentration or range of concentration of any

and all excipients.)

This will enable dosage form manufacturers to accurately compare raw materials from different vendors and will thereby facilitate batch-to-batch consistency in products reaching the consumer.

Back

Webster's Encyclopedic Unabridged Dictionary of the English Language

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...ch is external. 10. **externals**, external features, appearances, etc.; outward appearance; superficialities. *The externals of a religion attract the shallow and the extended.* [late ME; see EXTERN, -AL¹] —**ex·ter'nal·ly**, *adv.*

external au·ditory mea·tus, *Anat.* the canal leading from the opening in the external ear to the tympanic membrane. See diag. under **ear**.

external-com·bus·tion (ik stûr'nᵊl kəm bus'chən), *adj.* noting or pertaining to an engine, as a steam engine, in which fuel ignition takes place outside the cylinder, turbine, or the like, in which heat energy is transformed into mechanical force.

external ear', the outer portion of the ear, consisting of the auricle and the canal extending to the tympanic membrane. *Cf.* **ear**¹ (def. 1). See diag. under **ear**.

external hem'orrhoid, *Pathol.* See under **hemorrhoid**.

external il'iac ar'tery, *Anat.* See **iliac artery**.

ex·ter·nal·i·sa·tion (ik stûr'nᵊl ə zā'shən), *n. Chiefly Brit.* **externalization**.

ex·ter·nal·ise (ik stûr'nᵊlīz'), *v.t.*, **-ised**, **-is·ing**. *Brit.* **externalize**.

ex·ter·nal·ism (ik stûr'nᵊlīz'əm), *n.* attention or devotion to externals: excessive attention to externals. [EXTERNAL + -ISM] —**ex·ter'nal·ist**, *n.*

ex·ter·nal·i·ty (ek'stər nal'i tē), *n.*, *pl.* **-ties**. 1. the fact or quality of being external. 2. something that has an outward feature. 3. excessive attention to externals. [EXTERNAL + -ITY]

ex·ter·nal·i·za·tion (ik stûr'nᵊlī zā'shən), *n.* 1. the act or process of externalizing. 2. the quality or state of being externalized. 3. that which is externalized. *Also, esp. Brit.*, **externalisation**. [EXTERNALIZE + -ATION]

ex·ter·nal·ize (ik stûr'nᵊlīz'), *v.t.*, **-ized**, **-iz·ing**. to make external; embody in an outward form: *Mrs. Gaskell externalizes the relational capacity of the heroine.* 2. to regard as consisting of externals. 3. to regard or treat as being caused by externals; attribute to external causes: *to externalize one's difficulties.* 4. to direct (the personality) outward in social relationships. *Also, esp. Brit.*, **externalise**. [EXTERNAL + -IZE]

external jug'ular vein'. See under **jugular vein**.

external rela'tion, *Philos.* a relation between two entities such that if they had not been in this relation to each other, the nature of each would not necessarily have been different. *Cf.* **internal relation**.

ex·cep·tive (ek'stər ə sep'tiv), *adj. Physiol.* pertaining to exteroceptors, the stimuli acting upon them, or the nerve impulses initiated by them. [*extero-* (form of *L exterus* EXTERIOR) + (RE)CEPTIVE]

ex·cep·tor (ek'stər ə sep'tər), *n. Physiol.* a receptor responding to stimuli originating from outside the body. [*extero-* (see EXTEROCEPTIVE) + (RE)CEPTOR]

ex·ri·to·ri·al (eks'ter i tôr'ē əl, -tōr'-), *adj.* extraterritorial. [EX-¹ + TERRITORIAL] —**ex·ter'ri·to·ri·al'i·ty**, *n.* —**ex·ter·ri·to'ri·al·ly**, *adv.*

extinct (ik stiŋkt'), *adj.* 1. not existing now; that has died or died out: *an extinct species of fish.* 2. no longer in use; obsolete: *an extinct custom.* 3. extinguished; quenched; not burning. 4. having ceased to be in force; no longer active: *an extinct volcano.* [late ME *extinct(us)* put out, quenched, ptp. of *ex(s)tinguere* EXTINGUISH]

extinct, gone, vanished. See **dead**. 2. archaic. 3, 4.

extinction (ik stiŋk'shən), *n.* 1. the act of extinguishing. 2. the fact or condition of being extinguished or extinct. 3. suppression; abolition; annihilation: *the extinction of an army; the extinction of hopes.* 4. the act or process of becoming extinct; a coming to an end or dying out: *the extinction of a species.* 5. *Psychol.* the reduction or loss of a conditioned response as a result of the absence or withdrawal of reinforcement. [late ME *extinctio(u)n* < L *ex(s)tinctiōn-* (s. of *ex(s)tinctiō*). See EXTINCT, -ION]

extinction me'ter, *Photog.* an exposure meter measuring the intensity of light by the invisibility or faintness of one of a series of figures on a glass or sheet of celluloid of varying thickness.

extinctive (ik stiŋk'tiv), *adj.* tending or serving to extinguish. [EXTINCT + -IVE]

exine (ek'sīn, -sin), *n. Bot.* exine. [< L *ex(t)imus* outward + -INE²]

extinguish (ik stiŋk'gwish), *v.t.* 1. to put out (a fire, light, etc.); put out the flame of (something burning or lighted): *to extinguish a candle.* 2. to put an end to or bring to an end; wipe out of existence: *to extinguish hope.* 3. to obscure or eclipse, as by superior brilliancy: *Her beauty extinguished that of other women.* 4. *Law.* to discharge (a debt). 5. *Archaic.* to quench) + -ISH²] —**ex·tin'guish·a·ble**, *adj.* —**ex·tin'guish·ment**, *n.*

extinguish·er (ik stiŋ'gwi shər), *n.* 1. one who or that which extinguishes. 2. any of various portable devices for extinguishing fire: *a chemical extinguisher.* [EXTINGUISH + -ER¹]

extirpate (ek'stər pāt', ik stûr'pāt), *v.t.*, **-pat·ed**, **-pat·ing**. 1. to root out; eradicate; destroy totally; do away with. 2. to pull up by or as if by the roots; root up: *to extirpate a bad habit; to extirpate unwanted hair.* [< L *ex(s)tirpāt(us)* plucked up by the stem (ptp. of *ex(s)tirpāre*), equiv. to *ex-* EX-¹ + *stirp-* (s. of *stirps*) stem + *-ātus* -ATE¹] —**ex'tir·pa'tive**, *adj.* —**ex'tir·pa'tor**, *n.*

extol (ik stōl', -stol'), *v.t.*, **-tolled**, **-tol·ling**. to praise highly; laud; eulogize: *to extol the beauty of nature.* Also, **extoll'**. [late ME *extolle(n)* < L *extollī(ere)* to lift up, raise, equiv. to *ex-* EX-¹ + *tollere* to lift, take up] —**ex·tol'ler**, *n.* —**ex·tol'ling·ly**, *adv.* —**ex·tol'ment**, **ex·toll'ment**, *n.*

Syn. commend, glorify, exalt, celebrate. —**Ant.** disparage.

extor·sive (ik stôr'siv), *adj. Law.* serving or tending to extort: *extorsive measures.* [< L *extors(us)* (ptp. of *exterquere*; see EXTORT) + -IVE] —**ex·tor'sive·ly**, *adv.*

extort (ik stôrt'), *v.t.* 1. *Law.* a. to wrest or wring (money, information, etc.) from a person by violence, intimidation, or abuse of authority; obtain by force, torture, threat, or the like. b. to take illegally under color of office. 2. to compel (something) of a person by any thing: *Her charm and vivacity extorted their admiration.* [late ME (adj.) < L *extort(us)*, ptp. of *extorquēre*, equiv. to *ex-* EX-¹ + *torquēre* to twist] —**ex·tort'er**, *n.* —**ex·tor'tive**, *adj.*

Syn. 1. See **extract**.

ex·tor·tion (ik stôr'shən), *n.* 1. the act or an instance of extorting. 2. *Law.* the crime of obtaining money or some other thing of value under color of office, when none or not so much is due, or before it is due. 3. oppressive or illegal exaction, as of excessive price or interest: *the extortions of usurers.* 4. anything extorted. [ME *extorcion* < L *extortiōn-* (s. of *extortiō*). See EXTORT, -ION]

Syn. 1, 4. blackmail.

ex·tor·tion·ar·y (ik stôr'shə ner'ē), *adj.* characterized by or given to extortion. [EXTORTION + -ARY]

ex·tor·tion·ate (ik stôr'shə nit), *adj.* 1. exorbitant; grossly excessive: *extortionate prices.* 2. characterized by extortion, as persons: *extortionate moneylenders.* [EXTORTION + -ATE¹] —**ex·tor'tion·ate·ly**, *adv.*

ex·tor·tion·er (ik stôr'shə nər), *n.* a person who practices extortion. Also, **ex·tor'tion·ist**. [ME *extorcioner*. See EXTORTION, -ER¹]

ex·tra (ek'strə), *adj.* 1. beyond or more than what is usual, expected, or necessary; additional: *an extra edition of a newspaper; an extra price.* 2. larger or better than what is usual: *an extra binding.* —*n.* 3. something extra or additional: *the little amenities and extras that make life pleasant.* 4. an additional expense. 5. an edition of a newspaper other than the regular edition or editions. 6. something of superior quality: *The Italian sports car was an extra.* 7. *Motion Pictures.* a person hired by the day to play a minor part as a member of a mob or crowd. 8. an additional worker: *The company hired several extras in order to finish the work on time.* 9. Usually, **extras**. *Cricket.* a score or run not made from the bat, as a bye or a wide. —*adv.* 10. in excess of the usual or specified amount: *an extra high price.* 11. beyond the ordinary degree; unusually; uncommonly: *done extra well; extra large.* [? by shortening of EXTRAORDINARY]

extra-, a prefix meaning "outside," "beyond," freely used as an English formative: *extrajudicial; extraterritorial; extra-atmospheric.* Also, **extro-**. [< L, comb. form of *extrā* (adv. and prep.) outside (of), without]

ex·tra-at·mos·pher·ic (ek'strə at'məs fer'ik), *adj.* outside the earth's atmosphere.

ex·tra-base' hit' (ek'strə bās'), *Baseball.* a base hit that enables a batter to reach more than one base safely, as a two-base hit, three-base hit, or home run.

ex·tra-bold (ek'strə bōld'), *Print.* —*n.* 1. unusually heavy boldface type. —*adj.* 2. in extrabold. [EXTRA- + BOLD]

ex·tra-ca·non·i·cal (ek'strə kə non'i kəl), *adj. Eccles.* not included in the canon of Scripture. [EXTRA- + CANONICAL]

ex·tra-cap·su·lar (ek'strə kap'sə lər), *adj.* outside a capsule or capsular thing. [EXTRA- + CAPSULAR]

ex·tra-cel·lu·lar (ek'strə sel'yə lər), *adj. Biol.* outside a cell or cells. [EXTRA- + CELLULAR] —**ex'tra-cel'lu·lar·ly**, *adv.*

ex·tra-con·densed (ek'strə kən denst'), *adj. Print.* (of type) narrower than condensed type in proportion to its height.

ex'tra cov'er, *Cricket.* 1. the position of a fielder between mid off and cover point. 2. the fielder occupying this position. Also, **ex'tra cov'er point'**.

ex·tract (*v.* ik strakt'; *n.* ek'strakt), *v.t.* 1. to get, pull, or draw out, usually with special effort or force: *to extract a tooth.* 2. to deduce (a doctrine, principle, interpretation, etc.): *He extracted a completely personal meaning from what was said.* 3. to derive or obtain (pleasure, comfort, etc.) from a particular source: *He extracted satisfaction from the success of his sons.* 4. to take or copy out (matter), as from a book. 5. to make excerpts from (a book, pamphlet, etc.). 6. to extort (information, money, etc.): *to extract a secret from someone.* 7. to separate or obtain (a juice, ingredient, principle, etc.) from a mixture by pressure, distillation, treatment with solvents, or the like. 8. *Math.* to determine (the root of a quantity). —*n.* 9. something extracted. 10. a passage taken from a book, article, etc.; excerpt; quotation. 11. a solution or preparation containing the active principles of a drug, plant juice, or the like; concentrated solution: *vanilla extract.* 12. a drug, or the like: *beef extract.* [late ME < L *extract(us)* (ptp. of *extrahere*). See EX-¹, TRACT¹] —**ex·tract'a·bil'i·ty**, **ex·tract'i·bil'i·ty**, *n.* —**ex·tract'a·ble**, **ex·tract'i·ble**, *adj.*

Syn. 1. pry out. 6. evoke, educe, draw out, elicit. EXTRACT, EXACT, EXTORT, WREST imply using force to remove something. To EXTRACT is to draw forth something as by pulling, importuning, or the like: *to extract a confession by using third-degree methods.* To EXACT is to impose a penalty, or to obtain by force or authority, something to which one lays claim: *to exact payment, obedience.* To EXTORT is usually to wring something by intimidation or threats from an unwilling person: *to extort money by threats of blackmail.* To WREST is to take by force or violence in spite of active resistance: *The courageous minority wrested the power from their oppressors.* 7. withdraw, distill. 10. citation, selection. 11. decoction, distillation.

ex·tract·ant (ik strak'tənt), *n. Chem.* the substance extracted. [EXTRACT + -ANT]

ex·trac·tion (ik strak'shən), *n.* 1. the act or an instance of extracting. 2. the state or fact of being extracted: *In its extraction from the text the statement makes little sense.* 3. descent or lineage: *to be of foreign extraction.* 4. something extracted; extract. [late ME *extraccioun* < ML *extractiōn-* (s. of *extractiō*). See EXTRACT, -ION]

ex·trac·tive (ik strak'tiv), *adj.* 1. tending or serving to extract or based upon extraction: *the coal, oil, copper, and other extractive industries.* 2. capable of being extracted. 3. of or of the nature of an extract. —*n.* 4. something extracted. [EXTRACT + -IVE]

ex·trac·tor (ik strak'tər), *n.* 1. one who or that which extracts. 2. (in a firearm or cannon) the mechanism that, after firing, pulls an empty or unfired cartridge or shell case out of the chamber and brings it into place for action by the ejector. 3. a centrifuge for spinning wet laundry so as to remove excess water. 4. *Med., Dentistry.* an instrument for drawing out, extracting, or pulling. [EXTRACT + -OR²]

ex'tract print'ing. See **discharge printing**.

ex·tra·cur·ric·u·lar (ek'strə kə rik'yə lər), *adj.* 1. outside the regular curriculum: *extracurricular reading.* 2. of or pertaining to school activities exclusive of the regular academic course, as sports, singing in a glee club, etc. [EXTRA- + CURRICULAR]

ex·tra·dit·a·ble (ek'strə dī'tə bəl, ek'strə dī'-), *adj.* 1. capable of being extradited; subject to extradition: *an extraditable person.* 2. capable of incurring extradition: *an extraditable offense.* [EXTRADITE + -ABLE]

ex·tra·dite (ek'strə dīt'), *v.t.*, **-dit·ed**, **-dit·ing**. 1. to give up (a fugitive or prisoner) to another nation or authority. 2. to obtain the extradition of. [back formation from EXTRADITION]

ex·tra·di·tion (ek'strə dish'ən), *n.* the surrender of a fugitive from justice or a prisoner by one state or authority to another. [< F; see EX-¹, TRADITION]

ex'tra div'idend. See **special dividend**.

ex·tra·dos (ek'strə dos', -dōs', ek strā'dos, -dōs), *n., pl.* **-dos** (-dōz', -dōs), **-dos·es**. *Archit.* the exterior curve or surface of an arch or vault. Also called **back**. *Cf.* **intrados**. See diag. under **arch**. [< F, equiv. to *extra-* EXTRA- + *dos* back (< L *dorsum* DORSUM)]

ex·tra·dosed (ek strā'dost), *adj.* (of an arch) having a curved intrados the form of which is repeated by the extrados. [EXTRADOS + -ED²]

ex·tra·em·bry·on·ic (ek'strə em'brē on'ik), *adj.* situated outside the body of the embryo; developed in connection with the embryo but not as a structural part of it. Also, **ex'tra·em'bry·on'al**. [EXTRA- + EMBRYONIC]

ex·tra·flo·ral (ek'strə flôr'əl, -flōr'-), *adj. Bot.* situated outside the flower, as a nectary. [EXTRA- + FLORAL]

ex·tra·ga·lac·tic (ek'strə gə lak'tik), *adj.* outside the Milky Way system: *an extragalactic nebula.* [EXTRA- + GALACTIC]

extragalac'tic neb'ula, *Astron.* nebula (def. 1c).

ex·tra·ju·di·cial (ek'strə jōō dish'əl), *adj.* 1. outside of judicial proceedings; beyond the action or authority of a court. 2. beyond, outside, or against the usual procedure of justice; legally unwarranted: *an extrajudicial penalty.* [EXTRA- + JUDICIAL] —**ex'tra·ju·di'cial·ly**, *adv.*

ex·tra·le·gal (ek'strə lē'gəl), *adj.* being beyond the province or authority of law. [EXTRA- + LEGAL] —**ex'tra·le'gal·ly**, *adv.*

ex·tra·mar·i·tal (ek'strə mar'i tᵊl), *adj.* pertaining to sexual relations with someone other than one's spouse. [EXTRA- + MARITAL]

ex·tra·met·ri·cal (ek'strə me'tri kəl), *adj. Pros.* containing one or more syllables in addition to those required by the meter: *an extrametrical line.* [EXTRA- + METRICAL]

ex·tra·mun·dane (ek'strə mun'dān, -mun dān'), *adj.* beyond our world or the material universe. [< LL *extrāmundān(us)* beyond the world. See EXTRA-, MUNDANE]

ex·tra·mu·ral (ek'strə myōōr'əl), *adj.* 1. involving representatives of more than one school: *extramural athletics.* 2. outside the walls or boundaries, as of a city or town or a university: *extramural teaching; an extramural church.* *Cf.* **intramural** (defs. 1, 2). [EXTRA- + MURAL] —**ex'tra·mu'ral·ly**, *adv.*

ex·tra·ne·ous (ik strā'nē əs), *adj.* 1. introduced or coming from without; not belonging or proper to a thing; external; foreign. 2. not pertinent; irrelevant: *an extraneous remark; extraneous decoration.* [< L *extrāneus* external, foreign, equiv. to *extr(a)-* EXTRA- + *-āneus* -ANEOUS] —**ex·tra'ne·ous·ly**, *adv.* —**ex·tra'ne·ous·ness**, *n.*

Syn. 1. extrinsic, adventitious, alien. 2. inappropriate, nonessential, superfluous. —**Ant.** 1. intrinsic. 2. pertinent.

ex·tra·nu·cle·ar (ek'strə nōō'klē ər, -nyōō'-), *adj.* pertaining to or affecting the parts of a cell outside the nucleus. [EXTRA- + NUCLEAR]

ex·traor·di·nar·y (ik strôr'dᵊner'ē, ek'strə ôr'dᵊner'ē), *adj.* 1. beyond what is usual, ordinary, regular, or established: *extraordinary powers given to the President in wartime; unexpected extraordinary costs.* 2. exceptional in character, amount, extent, degree, etc.; noteworthy; remarkable: *extraordinary weather; extraordinary speed; an extraordinary man.* 3. (of an official, employee, etc.) outside of or additional to the ordinary staff; having a special, often temporary task or responsibility: *an extraordinary delegate to the Vatican.* [late ME *extraordinarie* < L *extrāordinārī(us)* beyond what is ordinary. See EXTRA-, ORDINARY] —**ex·traor·di·nar·i·ly** (ik strôr'dᵊnâr'ə lē, ek'strə ôr'-), *adv.* —**ex·traor'di·nar'i·ness**, *n.*

Syn. 1. inordinate. 2. uncommon, singular, rare, phenomenal, special, signal, egregious. —**Ant.** 1, 2. common, usual.

extraor'dinary ju'bilee. See under **jubilee**¹ (def. 5b).

extraor'dinary ray', *Optics, Crystall.* the part of a doubly-refracted ray that has changed speed and vibrations in the principal plane of the crystal.

extraor'dinary wave', *Radio.* (of the two waves into which a radio wave is divided in the ionosphere under the influence of the earth's magnetic field) the wave with characteristics more different from those that the undivided wave would have exhibited in the absence of the magnetic field. Also called **X-wave**. *Cf.* **ordinary wave**.

ex·tra·phys·i·cal (ek'strə fiz'i kəl), *adj.* outside the physical; not subject to physical laws. [EXTRA- + PHYSICAL]

ex·trap·o·late (ik strap'ə lāt', ek'stra pə-), *v.*, **-lat·ed**, **-lat·ing**. —*v.t.* 1. *Statistics.* to estimate the value of a variable outside its tabulated or observed range. 2. to infer (that which is not known) from that which is known; conjecture. —*v.i.* 3. to perform extrapolation. [EXTRA- + (INTER)POLATE] —**ex·trap'o·la'tive**, **ex·trap·o·la·to·ry** (ik strap'ə lə tôr'ē, -tōr'ē), *adj.* —**ex·trap'o·la'tor**, *n.*

ANALYTICAL CHEMISTRY HANDBOOK

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Kinetic masking utilizes differences in rates of complex formation or dissociation. For example, ice-cold solutions at pH 2 of Ni-EDTA and Al-EDTA are only slowly dissociated by added Bi(III) ion, permitting Ni to be determined in the presence of Cd, Co, Cu(II), Mn(II), Pb, and Zn.

2.1.3 Demasking

For the major part, masking reactions that occur in solutions and lead to soluble compounds are equilibrium reactions. They usually require the use of an excess of the masking agent and can be reversed again by removal of the masking agent. The freeing of previously masked ionic or molecular species has been called *demasking*. This merits consideration in regard to its use in analysis. Masking never completely removes certain ionic or molecular species, but only reduces their concentrations. The extent of this lowering determines which color or precipitation reactions can be prevented. A system masked against a certain reagent is not necessarily masked against another but more aggressive reagent. It is therefore easy to see that masked reaction systems can also function as reagents at times (e.g., Fehling's solution, Nessler's reagent).

The methods used in demasking are varied. One approach is to change drastically the hydrogen ion concentration of the solution. The conditional stability constants of most metal complexes depend greatly on pH, so that simply raising or lowering the pH is frequently sufficient for selective demasking. In most cases a strong mineral acid is added, and the ligand is removed from the coordination sphere of the complex through the formation of a slightly ionized acid as with the polyprotic (citric, tartaric, EDTA, and nitriloacetic) acids.

Another type of demasking involves formation of new complexes or other compounds that are more stable than the masked species. For example, boric acid is used to demask fluoride complexes of tin(IV) and molybdenum(VI). Formaldehyde is often used to remove the masking action of cyanide ions by converting the masking agent to a nonreacting species through the reaction

$$CN^- + HCHO \rightleftharpoons OCH_2CN \qquad (2.19)$$

which forms glycollic nitrile. Pertinent instances are the demasking of $Ni(CN)_4^{2-}$ ions to Ni^{2+} ions by formaldehyde and the demasking of dimethylglyoxime (dmg) from $Pd(dmg)_2^{2-}$ ions by cyanide. Selectivity is evident in that $Zn(CN)_4^{2-}$ is demasked, whereas $Cu(CN)_3^{2-}$ is not.

Destruction of the masking ligand by chemical reaction may be possible, as in the oxidation of EDTA in acid solutions by permanganate or another strong oxidizing agent. Hydrogen peroxide and Cu(II) ion destroy the tartrate complex of aluminum.

Demasking methods for a number of masking agents are enumerated in Table 2.5.

2.2 EXTRACTION METHODS[11-13]

Most chemical reactions show poor selectivity as to the types of metal ions that take part. To improve the selectivity it is common to resort to extraction methods. Solutes have different solubilities in different solvents, and the process of selectively removing a solute from a mixture with a solvent is called *extraction*. The solute to be extracted may be in a solid or in a liquid medium, and the solvent used for the extraction process may be water, a water-miscible solvent, or a water-immiscible solvent. The selection of the solvent to be used depends upon the solute and upon the requirements of the experimental procedure. An ideal extraction method should be rapid, simple, and inexpensive to

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